EC	REP

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BIOMET®

One Surgeon. One Patient.™

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User Manual and
Package Insert

EBI Bone Healing System®
Model 2001

BIOMET®

Non-Invasive Stimulation
OPTIONS • EVIDENCE • EXPERIENCE

IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS BEFORE USING

When using electrical products, basic safety precautions should always be followed, including:

WARNING: To reduce the risk of electric shock, fire or potential injury:

1. Do not use while bathing.
2. Do not place or store product where it can fall or be pulled into a tub or sink.
3. Do not immerse the control unit, coil, battery charger/power unit, or the battery charger cradle in any liquid.
4. Do not reach for a product that has fallen into a liquid. Unplug from the wall outlet immediately.
5. Do not permit the battery charger to be connected when wet.
6. Do not drop the control unit, coil, battery charger/power unit, or the battery charger into any liquid.
7. Avoid touching the battery contacts when the battery charger cradle is plugged into an outlet.
8. Do not place the battery charger cradle in the bed with you if you are using the unit while you are sleeping.
9. Never operate this product if it has a damaged link cable, cord or plug, if it is not working properly, if it has been dropped and damaged, or dropped into any liquid. Return the product to EBI.
10. Keep all cords away from heated surfaces.
11. Never insert any object into any opening of the system.
12. Do not place the control unit or the battery charger in prolonged heat or direct sunlight (Normal operating temperature range is 0°C to 38°C, [32°F to 100°F], normal storage/transport temperature is -15°C to 45°C [5°F to 113°F]).
13. Connect this product to a properly grounded outlet (See GROUNDING INSTRUCTIONS).
14. Use this product only for its intended use as described in this manual.
15. Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be operated according to the EMC information provided in this instruction manual.

NOTE: *Call the Biomet Patient Support Department in New Jersey between 8:30 a.m. and 6:30 p.m. Eastern Time at 1-973-299-9300 with any questions or problems. Outside the United States contact your local EBI/Biomet Distributor.*

SAVE THESE INSTRUCTIONS

Contents:

Model 2001 Control Unit

FLX® Treatment Coil with straps (if applicable)

Connector cables

Belt and Pouch (if applicable)

Recharger base

Recharger Power Supply

User Manuals (2)

FLX® Gauge

Travel Card

Carrying Case

Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

For Prescription Use Only.

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EBI Model 2001 Bone Healing System®
Model 2001 and FLX® Flexible Treatment Coil

Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. For Prescription Use Only. Single prescription. Single patient use. Not for re-sale, re-use or re-distribution.

DESCRIPTION

The EBI Bone Healing System® Stimulator promotes healing by inducing weak pulsing electrical currents at the nonunion fracture site. These signals are generated by a low energy electromagnetic field created by passing specific electrical current pulses through a flexible treatment coil.

Electrical Requirements of Model 2001 Power Unit – USA/Americas

Input: 120V ∿ 60Hz 36W
Output: 17.8V ⎓ 1.5A.

Do not use any other power unit with the Model 2001 Bone Healing System.

ELECTRICAL REQUIREMENTS

Use the following power adapters with the Model 2001 Bone Healing System.

Model 2001A		**Australia**		
	Input:	240V ∿	50Hz	36W
	Output:	17.8V ⎓	1.5A	
Model 2001E		**Europe**		
	Input:	230V ∿	50Hz	36W
	Output:	17.8V ⎓	1.5A	
Model 2001J		**Japan**		
	Input:	100V ∿	50Hz	36W
	Output:	17.8V ⎓	1.5A	
Model 2001U		**United Kingdom**		
	Input:	240V ∿	50Hz	36W
	Output:	17.8V ⎓	1.5A	

SYSTEM COMPONENTS

CONTROL UNIT

The EBI Bone Healing System® Stimulator control unit operates on nickel metal hydride, rechargeable batteries which allow for ambulatory use. The control unit contains the operating electronics programmed for the FLX® Flexible Treatment Coil. It includes an audible and visible self checking alarm mechanism to alert the patient if the unit is not functioning properly.

The control unit is designed to store the patient's daily usage information. Patients are encouraged to bring the control unit and treatment coil to each follow-up visit to allow the prescribing physician to review their treatment regimen.

NOTE: *The control unit may be worn comfortably on a belt or the waist using the Belt Pouch when the patient is ambulatory.*

BATTERY CHARGER CRADLE

The battery charger cradle is powered by the battery charger/power unit adaptor and is designed to recharge the control unit batteries. Its design also allows the control unit to be used in a treat and charge situation (i.e., while sleeping, sitting) (See TREATING AND CHARGING STEP 3 pg. 11).

BATTERY CHARGER/POWER UNIT

The battery charger/power unit is powered by normal house current and is designed to provide power to the charger cradle. Power unit must be unplugged from wall outlet to be disconnected.

LINK CABLE

The link cable connects the control unit to its FLX® Flexible Treatment Coil. The link cable supplied is a 33" (83.8cm) cable. Link cables are also available in 12" and 48" lengths. For either a 12" (30.5cm) or 48" (121.9cm) cable, phone the Biomet Patient Support Department at 1-973-299-9300. Outside the United States contact your local EBI/Biomet Distributor.

FLX® FLEXIBLE TREATMENT COIL

The FLX® Flexible Treatment Coil is an encased wire coil that may be incorporated into a cast, over a cast or brace, or when a cast is not utilized, may be applied directly to the skin. A specific electrical current is delivered to the coil by the control unit. The coil then delivers the therapeutic electromagnetic signal to the nonunion fracture site.

GROUNDING PLUG

This product is equipped with a grounding plug with the exception of the Model 2001E. The battery charger/power unit should be plugged into a wall outlet that is properly installed and grounded. In the event of an electrical short circuit, grounding reduces the risk of electric shock by providing an escape wire for the electric current.

If it is necessary to use an extension cord, use an extension cord that has a 3-blade grounding plug and a 3-slot receptacle that will accept the plug on the product. Do not use damaged cords.

Not for use by patients who are pregnant or becoming pregnant

Not recommended for patients with certain types of pacemakers or implantable defibrillators

FULL PRESCRIBING INFORMATION

The mechanism of action behind the PEMF technology involves the upregulation of factors that modulate normal bone healing. PEMF increases a number of factors such as TGF- $ß_1$, BMP-2 and BMP-4, which are normal physiological regulators of the various stages of bone healing, including angiogenesis, chondrogenesis and osteogenesis.

INDICATIONS FOR USE

The EBI Bone Healing System® Stimulator is indicated for the treatment of fracture nonunions, failed fusions, and congenital pseudarthrosis in the appendicular system. A nonunion is considered to be established when there are no visibly progressive signs of healing. The original 1979 PMA study included 146 patients with nonunion fractures. These difficult fractures were characterized as follows: 2.3 average number of prior surgeries and an average of thirty-seven months (median twenty months) since original injury. These patients were followed for a minimum of four years (average seven years) from the date of treatment termination, with a success rate of 63.5%. Even though long term follow-up requirements were not included in the original study designs, a follow-up rate of 82% was achieved. Forty-three (43) of the original 48 patients in the congenital pseudarthrosis study were classified by Bassett[1] who defined the tibial lesions as Type I (n=6), Type II (n=19) and Type III (n=18), with Type III being the most severe and recalcitrant to treatment. The success rate for Bassett Type I lesions was 66.7%, Bassett Type II lesions 57.9% and Bassett Type III lesions 22.2%. The long term post treatment follow-up for the congenital pseudarthrosis study patient population (n=48) was to skeletal maturity or the age of 18. The study had an 87.5% follow-up rate.

CONTRAINDICATIONS

A. Nonunion fractures in which a synovial pseudarthrosis (fluid filled gap) exists.
B. Under certain conditions, electromagnetic stimulation could inhibit the output of some demand pacemakers or implantable defibrillators. Therefore, it is not recommended for patients with certain types of pacemakers or implantable defibrillators. Patients should be cautioned to avoid coming in close proximity to pacemaker or defibrillator wearers during stimulation.
C. Use of the EBI Bone Healing System® Stimulator on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.

WARNINGS

A. The long term effects of exposure to low level magnetic fields are not known. Routine use of The EBI Bone Healing System® Stimulator for over 20 years has indicated no known risks.
B. During the treatment of patients with open epiphyses, when the epiphysis is in the pulsing field, physicians are advised that the epiphyseal growth plates should be monitored for possible effects.
C. Use of the EBI Bone Healing System® Stimulator for spine and skull has not been evaluated.
D. To reduce the risk of potential injury:
    1. AVOID touching the battery charger contacts when the battery charger is plugged into a wall outlet.
    2. DO NOT place the battery charger in bed if treating while sleeping.
E. The control unit and battery charger are electrically live when connected together and the battery charger is plugged into an outlet. To reduce the risk of serious injury by electric shock patients are advised:
    1. DO NOT permit the battery charger to be connected when wet.
    2. DO NOT immerse the control unit, the coil or the battery charger in water or any liquid.

1. Bassett CAL, N Caulo and J Kort, “Congenital pseudarthrosis of the tibia: Treatment with pulsing electromagnetic fields”. Clinical Orthop, 154: 136-149,1981.

PRECAUTIONS

The following conditions may compromise a successful treatment outcome.

A. Nonunion fractures with gaps in excess of 1 cm.

B. Presence of fixation devices made from magnetic materials. (Most presently used internal or external fixation devices are constructed of 316L S.S., titanium alloys, and cobalt-chromium alloys which are non-magnetic and, therefore, compatible with the EBI Bone Healing System® Stimulator.)

ADVERSE EFFECTS

None known.

DIRECTIONS FOR USE

Follow the treatment schedule prescribed by your doctor - normally ten (10) hours per day.

Your compliance with the recommended ten (10) hours per day treatment is very important. A review of the clinical data demonstrates that less than the recommended use of this device possibly results in an increase in the time to heal your fracture. (P790002/S012)

If you are unable to treat for ten continuous hours, it is recommended that you break up the total treatment time into more than one session.

You should:

- Turn the control unit off when finished with your session
- When ready to resume treating, turn the control unit on. The display will indicate the treatment time you have completed and keep track of your cumulative treatment time for the day
- If you do not finish ten hours in that day, then use the RESET button to return the time to zero (See RESET BUTTON)

Remember, if the treatment is administered longer than the prescribed amount (ten hours), the additional time cannot be applied for future days. Example: If you used the system for multiple sessions totaling 14 hours one day, you should not abbreviate the next day's cumulative treatment time to six hours.

For your convenience, your daily treatment time is displayed continuously in hours and minutes. After ten hours of treatment, the display will read "10:00", and beep three (3) times, and then shut off automatically.

Following completion of your daily treatment, you should do the following:

1. Make sure the control unit is off. If you have completed 10 hours, the unit will automatically shut off. With less than 10 hours of treatment, you will need to manually turn the control unit off.
2. Insert the control unit firmly into the battery charger cradle to recharge the batteries for your next treatment (See BATTERY CHARGING).

The EBI Bone Healing System® Stimulator may be used at home or at work. Your schedule and lifestyle will determine the best time for using the system. Many people find it convenient to treat while they are sleeping.

- EBI Pre Market Approval Data (P790002/S012)

NOTE: This is a single patient use device, do not reuse. For Prescription Use Only. The EBI Bone Healing System® Stimulator is a durable therapeutic electrical device intended for single patient use only under a prescription. Treatment at home or in another appropriate or similar setting is acceptable. The device cannot be reprocessed, i.e., disinfected, sterilized, etc. with the intent to be used by another patient or for treatment other than prescribed.

RECOMMENDED CONCURRENT FRACTURE MANAGEMENT

The EBI Bone Healing System® Stimulator works best when motion of the fracture site is minimized or nonexistent. For most patients this immobilization is achieved by applying a well molded plaster or synthetic cast at the beginning of treatment (together with initial non-weight bearing, if it is the lower extremity).
The following methods of fracture immobilization have been most effective:

- ankle/tarsals/metatarsals: short leg cast, or rigid internal fixation
- tibia: long leg cast (short leg cast with rigid fixation), or stable internal fixation or external fixation
- shoulder/clavicle: brace or abduction splint or internal fixation or figure 8 immobilization
- humerus: stable internal fixation and/or adequate immobilization with controlled rotation
- scaphoid/wrist: long arm cast with thumb spica (short arm cast with rigid fixation), or stable internal fixation
- carpals/metacarpals/phalanges: cast or internal fixation or external fixation

WEIGHT BEARING GUIDELINES

Immediate weight bearing is recommended for “stable” fractures (less than five degrees of motion in any plane and/or stable internal fixation). Initial non-weight-bearing is recommended for “unstable” fractures (greater than five degrees of motion).
Allow six to twelve weeks for the progression of trabecular bridging with the counterproductive effects of tensile loading (Fuzziness at the fracture gap will be noted radiographically).

FRACTURE HEALING IN RESPONSE TO PEMFs

- Unlike fresh fractures, the healing of nonunions treated with pulsing electromagnetic fields (PEMFs) does not involve external callus formation. Rather, the healing is more endosteal or “inside out”, with the changes occurring within the fracture gap tissues and in the adjacent bone ends.

The bone healing process typically progresses in the following manner under PEMF treatment:

- Triggering calcification of the fibrocartilage in the fracture gap is an early PEMF effect. Radiographically this calcification is evidenced by the appearance of fuzziness in the gap space. The fuzziness varies in amount and rate of appearance. Concurrently, new blood vessels penetrate the calcified fibrocartilage, and the sclerotic bone flanking the gap begins to resorb (sclerolysis). These effects are normally observed approximately one to three months after treatment is initiated.

NOTE: *This early healing may be disrupted by injudicious loading and motion due to inadequate immobilization.*

FRACTURE HEALING IN RESPONSE TO PEMFs (cont'd)

- The second stage of healing is indicated by the appearance of consolidated bone stress lines that bridge the fracture gap. This bridging may appear initially, but should progress until cortical continuity occurs in all cortices as visualized on AP and lateral x-rays. Once cortical continuity is established and clinical union occurs (i.e. no motion), the PEMFs treatment may be discontinued. These effects are normally observed approximately three to eight months after treatment is initiated. At this point, the patient should be put on a program of guarded rehabilitation to prevent refracture.
- Subsequent remedullarization and remodeling occurs according to Wolff's Law and may take from twelve to twenty-four months to complete.

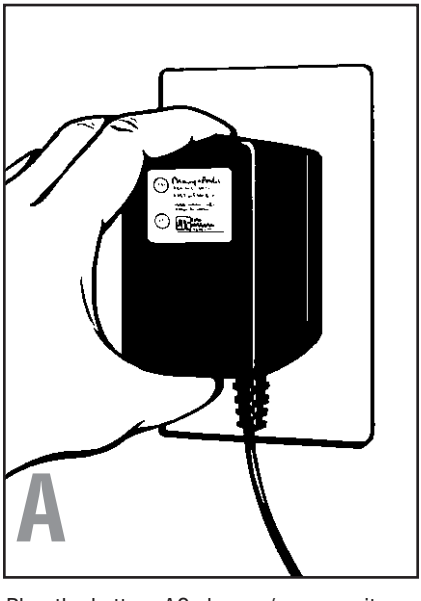
OPERATING INSTRUCTIONS

Before using the EBI Bone Healing System® Stimulator for the first time, the control unit should be charged.

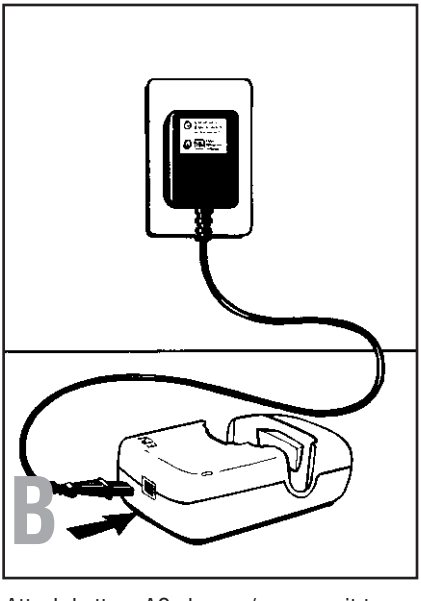
STEP 1:

BATTERY CHARGING

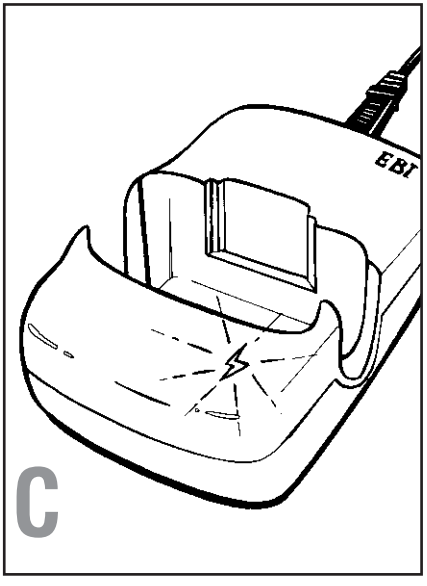
The EBI Bone Healing System® Stimulator runs on nickel metal hydride batteries. *Before treating with the system,* the patient will need to charge the batteries to a full charge. At room temperatures (24˚C [75˚F]), charging may take up to two hours. In warm temperatures (29˚C [85˚F]), the unit may take up to five hours to charge.



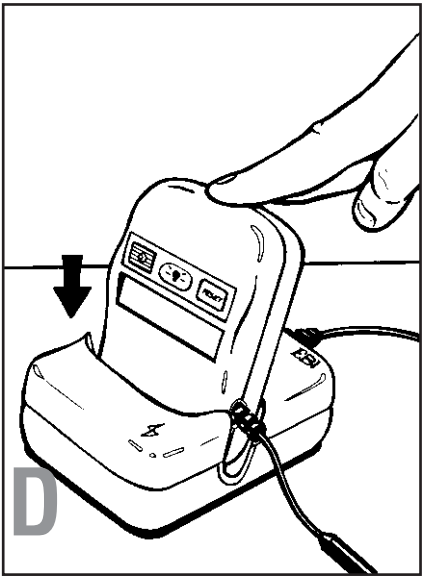
Plug the battery AC charger/power unit into a grounded wall outlet.



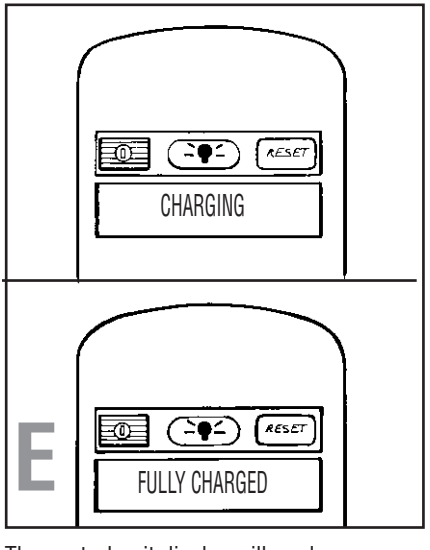
Attach battery AC charger/power unit to the battery charger cradle.



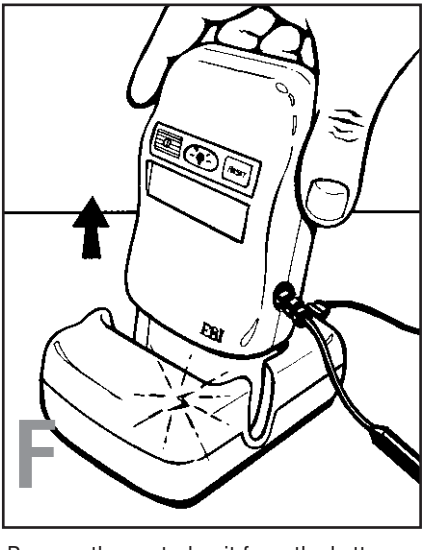
A green light on the cradle will illuminate indicating that the charger is connected to household power.



Place the control unit into the battery charger cradle as illustrated. Make sure the control unit is turned off.



The control unit display will read "CHARGING". When the control unit is fully charged, the display will read "FULLY CHARGED". The EBI Bone Healing System® Stimulator is now ready for daily treatment.

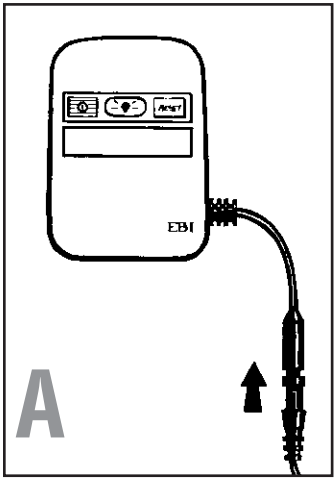


Remove the control unit from the battery charger cradle. The control unit is now ready for connection to the link cable and treatment coil.

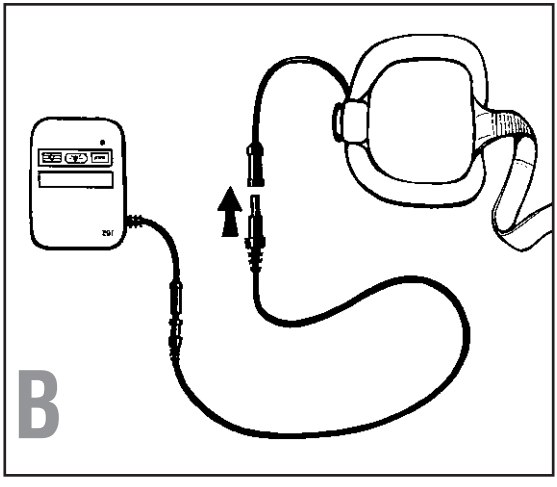
STEP 2:

PREPARING THE SYSTEM TO BEGIN TREATMENT

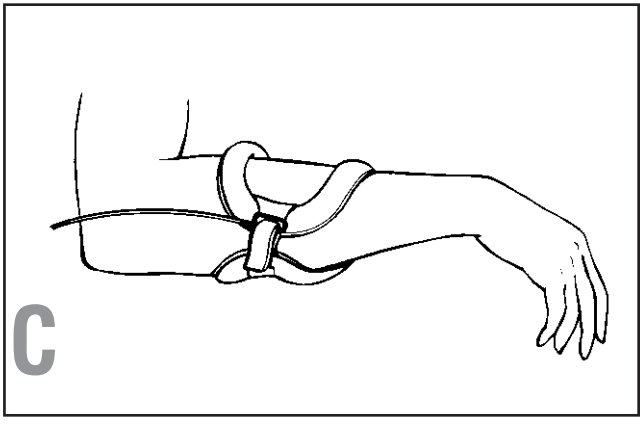
The link cable arrives disconnected from the control unit.



Connect one end of the link cable to the control unit cable as illustrated.



After confirming that the link cable is properly connected to the control unit, connect the other end of the link cable to the FLX® Flexible Treatment Coil. This connection allows for simple quick disconnect and reconnect by the patient.



Next, position the FLX® Flexible Treatment Coil over the fracture site. The entire fracture site should be centered within the coil treatment window.

STEP 3:

TREATING AND CHARGING

Patients may treat with the system while recharging the batteries. When the patient treats and charges at the same time, the treatment time and charging message will be displayed. To treat and charge, patients should:

1. Turn the control unit on.
2. Follow instructions A - E from Step 1. (Page 8)

NOTE: *If treating while the control unit is connected to the battery charger cradle, the control unit display will read "TREATING 00:00 and CHARGING". Once the patient has completed the treatment, he should turn the control unit off, and leave it connected to the battery charger cradle to continue charging the batteries, if it is not displaying "FULLY CHARGED".*

STEP 4:

RECHARGING THE BATTERIES

The average daily treatment time supplied by the batteries in the control unit will vary according to the size of FLX® coil being used. All coils should deliver a minimum treatment time of ten hours per charge, except the FLX® 5, which will deliver five hours of treatment per charge. At room temperatures (24°C [75°F]), charging may take up to two hours. In warm temperatures (29°C [85°F]), the unit may take up to five hours to charge.

After daily treatment, patients should do the following:

A. Turn the control unit **off**.

B. Follow instructions A-E from Step 1 (Pages 8 & 9).

C. It is not necessary to disconnect the control unit from the charger cradle once fully charged. The control unit can remain in the battery charger cradle until the patient's next treatment session.

NOTE: *The batteries cannot be overcharged. If the control unit is in the battery charger cradle and the batteries are already fully charged, the charger will terminate the recharging process early. This will be indicated by the control unit display reading "FULLY CHARGED" when charging is complete. Therefore, do not be concerned if the batteries are inadvertently charged more than once.*

When the batteries need recharging, the following will occur:

1. The display will read "RECHARGE BATTERY" and 10 short beeps will sound. After 10 seconds, the beep will stop and the display will shut off.

2. Until the batteries are recharged, "RECHARGE BATTERY" will appear on the display each time the control unit is turned on. After the third time the patient turns the unit on without recharging, "RECHARGE BATTERY" will appear and alternate with "PLEASE CALL EBI 1-800-526-2579". If patients need assistance with recharging, they should call the 800 number and ask to speak to a Patient Support Representative. Outside the United States contact your local EBI/Biomet Distributor, or call 1-973-299-9300.

3. Only after the patient places the control unit into the battery charger cradle for recharging will the message automatically clear.

4. When the control unit has been fully charged, it may be removed for ambulatory treatment, or left in the battery charger cradle and turned on for nonambulatory use.

Alternates with

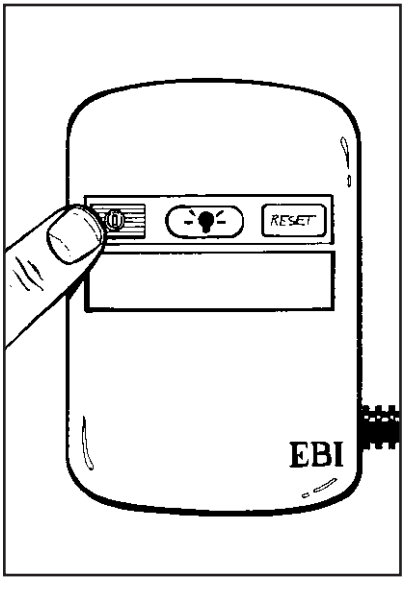
NOTE: *Every 14 days the charger will automatically refresh the batteries by completely depleting them before it begins charging. When this occurs, the control unit display will read "REFRESHING". Once the system has refreshed the batteries, the control unit display will read "CHARGING", and the charging process will begin. The refresh mode will take a few hours depending on the size of the* FLX® *Flexible Treatment Coil being used.*

KEYPAD FUNCTIONS

ON/OFF BUTTON

Each time the ON/OFF button is pressed, an audible beep will be heard. To turn the control unit on, press the on/off button one time. Pressing this button a second time will turn the system off. Every time the control unit is turned on, the display will indicate the following sequence:

1. "EBI RECOMMENDS 10 HOURS PER DAY" for the 2001 BHS.
2. "AVG HR/DAY 00:00" - This is the daily treatment average since the patient's treatment started.
3. "DAYS USED 000" - This is the total number of days of treatment.
4. "DAYS UNUSED 000" - This is the total number of days when there was no treatment.
5. "TREATING 00:00" - This is the cumulative number of hours of treatment in the present or previous treatment session, provided that the reset button has not been pressed (see RESET BUTTON).

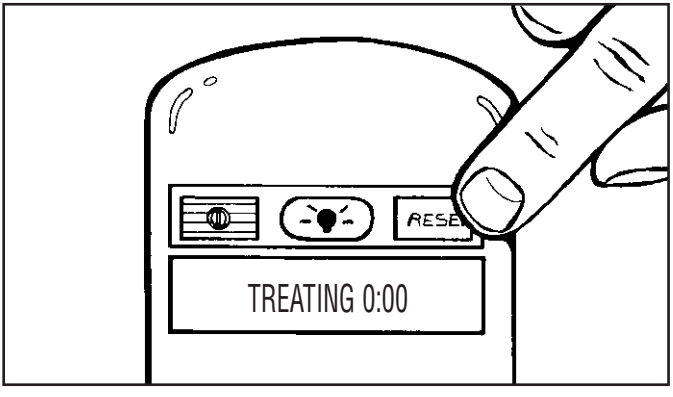


1. EBI RECOMMENDS 10 HOURS PER DAY
2. PATIENT USAGE AVG HR/DAY 00:00
3. PATIENT USAGE DAYS USED 000
4. PATIENT USAGE DAYS UNUSED 000
5. TREATING 0:00

RESET BUTTON

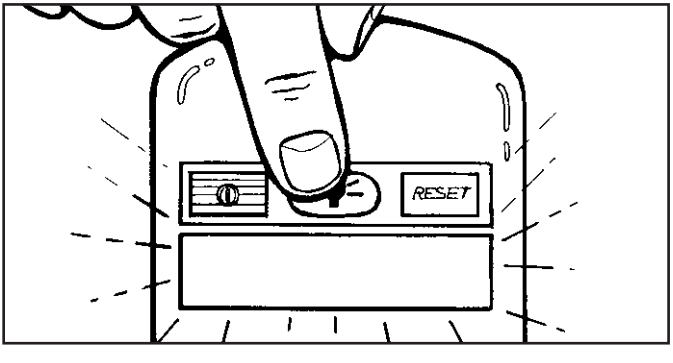
The system is designed with a reset function to allow the daily timer to be reset to zero. Should the patient not finish the ten hours of treatment in one day, he/she presses the RESET button for two (2) beeps and the daily timer will go back to zero in preparation for the next treatment session. The treatment time will be retained on the display unless the RESET button is depressed for two audible beeps.

To avoid the accidental reset of the daily time, the RESET button has a one second delay. When pressed, the RESET button will beep. To clear the time back to zero, continue holding the button until a second beep is heard (approximately one second). Release the RESET button. This will clear the time back to 0:00. The display will then read “TREATING 0:00”.



BACKLIGHT BUTTON

The system is designed with a backlight function to enhance the visibility of the LCD display in dim lighting. When pressed the BACKLIGHT button will beep, and the backlight will turn on for 5 seconds.



Following completion of your daily treatment, you should do the following:

1. Make sure the control unit is off. If you have completed 10 hours, the unit will automatically shut off. With less than 10 hours of treatment, you will need to manually turn the control unit off.

2. Insert the control unit firmly into the battery charger cradle to recharge the batteries for your next treatment (See BATTERY CHARGING).

The EBI Bone Healing System® Stimulator may be used at home or at work. Your schedule and lifestyle will determine the best time for using the system. Many people find it convenient to treat while they are sleeping.

TROUBLESHOOTING SYSTEM MESSAGES

Allow up to one minute for the display message to change after taking corrective action.

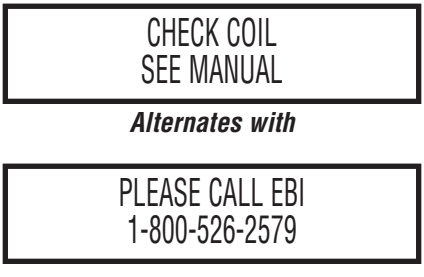
• "RECHARGE BATTERY" If this message appears, the batteries need to be recharged. This message will only appear during a treatment session. In order to recharge the batteries and continue treatment, ensure that the control unit is on. Refer to Step 4 "RECHARGING THE BATTERIES" (P. 11), repeating 1-4.

“CHECK CONNECTORS SEE MANUAL”

This message, accompanied by 10 short audible beeps, appears when the control unit is not properly connected to the FLX® Flexible Treatment Coil. Be sure to check all connections between the control unit, link cable and the treatment coil. If the connection is not made, the unit will turn itself off. When the unit is turned back on and the message continues, check all connections again. If the problem is not corrected and the connection is not made, the message will stay on the display for 10 seconds and then turn off each time the control unit is turned on. After the third time of turning the unit on without correcting the problem, “CHECK CONNECTORS SEE MANUAL” will appear and alternate with “PLEASE CALL EBI 1-800-526-2579”. If you need assistance, you should call the 800 number and ask to speak to a Patient Support Representative. Outside the United States contact your local EBI/Biomet Distributor, or call 1-973-299-9300.

”CHECK COIL SEE MANUAL”

This message, accompanied by ten short audible beeps, appears when the FLX® Flexible Treatment Coil is damaged or inappropriately flexed. The message will stay on the display for 10 seconds and then turn off each time the control unit is turned on. After the third time of turning the unit on without correcting the problem, “CHECK COIL SEE MANUAL” will appear and alternate with “PLEASE CALL EBI 1-800-526-2579”. If you need assistance, you should call the 800 number and ask to speak to a Patient Support Representative. Outside the United States contact your local EBI/Biomet Distributor, or call 1-973-299-9300.

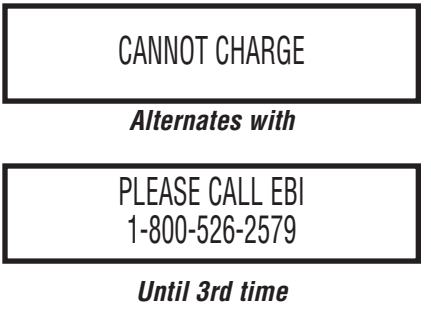


“CANNOT TREAT PLEASE CALL EBI 1-800-526-2579”

This message, accompanied by ten short audible beeps, appears when there is a hardware problem within the control unit. The message will stay on display for 10 seconds and then turn off each time the control unit is turned on. After the third time of turning the unit on without correcting the problem, “CANNOT TREAT” will appear and alternate with “PLEASE CALL EBI 1-800-526-2579”. If you need assistance, you should call the 800 number and ask to speak to a Patient Support Representative. Outside the United States contact your local EBI/Biomet Distributor, or call 1-973-299-9300.

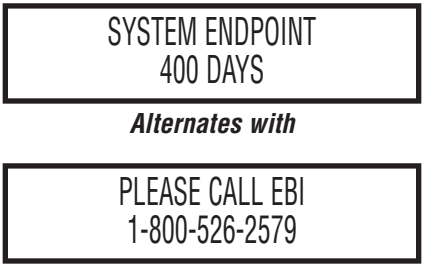
“CANNOT CHARGE PLEASE CALL EBI 1-800-526-2579”

This message, accompanied by 10 short audible beeps, appears when temperature is over 38 degrees C, under 0 degrees C or there is a hardware problem within the charger. The message will stay on the display for 10 seconds and then turn off each time the control unit is turned on. After the third time of turning the unit on without correcting the problem, “CANNOT CHARGE” will appear and alternate with “PLEASE CALL EBI 1-800-526-2579”. If you need assistance, you should call the 800 number and ask to speak to a Patient Support Representative. Outside the United States contact your local EBI/Biomet Distributor, or call 1-973-299-9300.



“SYSTEM ENDPOINT 400 DAYS”, “PLEASE CALL EBI 1-800-526-2579”

When the control unit reaches 400 days of treatment, the treatment signal is locked off. The display will read “SYSTEM ENDPOINT 400 DAYS” followed by “PLEASE CALL EBI 1-800-526-2579”. The display will turn off. This message will appear every time the control unit is turned on. At this point, the system should be discarded. It is recommended that you contact your Doctor’s office to inform him/her that you have reached this point in your treatment. See p.64 for Disposal Instructions. Outside the United States contact your local EBI/Biomet Distributor, or call 1-973-299-9300.



FLX® FLEXIBLE TREATMENT COILS

The FLX® Flexible Treatment Coil included with this EBI Bone Healing System® Stimulator was specifically chosen by Biomet based upon the location of the fracture, the vertical length of the fracture, the depth of signal penetration required to treat the fracture, and the anatomical size of the patient.

NOTE: *Included in each system is a Flexion Gauge for measuring the tolerances of the coil. The coil should not be flexed beyond the Flex Range of the gauge (the area indicated by green color).*

DEPTH OF PENETRATION SPECIFICATIONS FOR FLX® FLEXIBLE TREATMENT COILS FLX® 1, 2, 3, 4, 5, AND COILETTE COILS TOLERANCES

FLX® Coil		M/L Flexion	Depth of Penetration	Vertical Fracture Length
FLX® Mini Coilette (Phalangeal)	Minimum	2.5cm	2.5 cm	1.5 cm
	Maximum	3.5cm	2 cm	1.5 cm
FLX® Coilette (Small bones)	Flat	N/A	2.75 cm	4 cm
	Elliptical	N/A	3.5 cm	4 cm
	Saddle	N/A	3.5 cm	2 cm
FLX® XL Coilette	Flat	N/A	3.5 cm	6 cm
	Elliptical	5 cm	4.25 cm	6 cm
	Saddle	7.5 cm	5.5 cm	4 cm
FLX® 1 (Scaphoid)	Minimum	9 cm	6.5 cm	7 cm
	Maximum	13 cm	5.5 cm	6 cm
FLX® 1-1 (Elliptical)	Minimum	8 cm	5 cm	12 cm
	Maximum	10 cm	4 cm	12 cm
FLX® 1-2 (Metatarsal)	Minimum	9 cm	6.5 cm	7 cm
	Maximum	13 cm	5.5 cm	6 cm
FLX® 1-3 (Clavicle)	Minimum	120°	3 cm	5 cm
	Maximum	150°	3 cm	5 cm
FLX® 2	Minimum	8 cm	8 cm	10 cm
	Maximum	11 cm	7 cm	10 cm
FLX® 2-1 (Elliptical)	Minimum	10 cm	5 cm	16 cm
	Maximum	12 cm	4.5 cm	14 cm
FLX® 2-2 (Metatarsal)	Minimum	8 cm	8 cm	10 cm
	Maximum	11 cm	7 cm	10 cm
FLX® 2-3 (Clavicle)	Minimum	120°	4 cm	8 cm
	Maximum	150°	4 cm	8 cm
FLX® 2-4 (Ankle)	Minimum	8 cm	8 cm	10 cm
	Maximum	11 cm	7 cm	10 cm
FLX® 2-5 (Shoulder)	Minimum	8 cm	8 cm	10 cm
	Maximum	11 cm	7 cm	10 cm
FLX® 3	Minimum	5 cm	7 cm	7 cm
	Maximum	9 cm	5.5 cm	6 cm
FLX® 3-5 (Shoulder)	Minimum	5 cm	7 cm	7 cm
	Maximum	9 cm	5.5 cm	6 cm
FLX® 4	Minimum	9.25 cm	10 cm	12 cm
	Maximum	14.5 cm	8 cm	8 cm
FLX® 4-1 (Elliptical)	Minimum	12 cm	6 cm	22 cm
	Maximum	14 cm	6 cm	18 cm
FLX® 4-4 (Ankle)	Minimum	9.25 cm	10 cm	12 cm
	Maximum	4.5 cm	8 cm	8 cm
FLX® 4-5 (Shoulder)	Minimum	9.25 cm	10 cm	12 cm
	Maximum	14.5 cm	8 cm	8 cm
FLX® 5 (Femur)	Minimum	13 cm	12 cm	10 cm
	Maximum	20 cm	10 cm	10 cm

Specialty coils are for applications where the standard straps may be too difficult to apply. Each specialty FLX® coil features one (1) snap at all four corners of the coil and comes pre-assembled to fit the right side of the body but the same straps may be easily switched for left side applications.

NOTE: *Not all coils need to have straps switched.*

Fracture Type	**Specialty Coil Type**
Long Vertical Fractures	FLX® 1-1 or 2-1 or 4-1
Metatarsals	FLX® 2-1 or 2-2
Clavicle	FLX® 1-3 or 2-3
Ankle/Elbow	FLX® 2-4 or 4-4
Proximal Humerus/Shoulder	FLX® 2-5 or 3-5 or 4-5

Coil Application Instructions for the FLX®-1, FLX®-2, FLX®-3, FLX®-4 and FLX®-5 Coils

Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5001	FLX®-1	0100	Metatarsals, Radius, Ulna, Scaphoid, Metacarpals
5210	FLX®-2	0200	Humerus, Tibia, Fibula, Radius, Ulna
5310	FLX®-3	0300	Radius, Ulna, Humerus, Metatarsals, Tibia/Fibula
5410	FLX®-4	0400	Femur, Tibia/Fibula, Humerus
5510	FLX®-5	5500	Femur

Flexion Gauge Instructions for FLX®-1, FLX®-2, FLX®-3, FLX®-4 & FLX®-5 Coils

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be checked for the proper shape.

1) Place the coil at the treatment site and shape for best fit. Coil should be bent only in one direction. Do not kink or twist the coil.

2) Remove the shaped coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite coil edge should fall within the green zone in the area marked “FLEXION RANGE”. Each Flexion Gauge has a chart of coil tolerances with depth of penetration data.

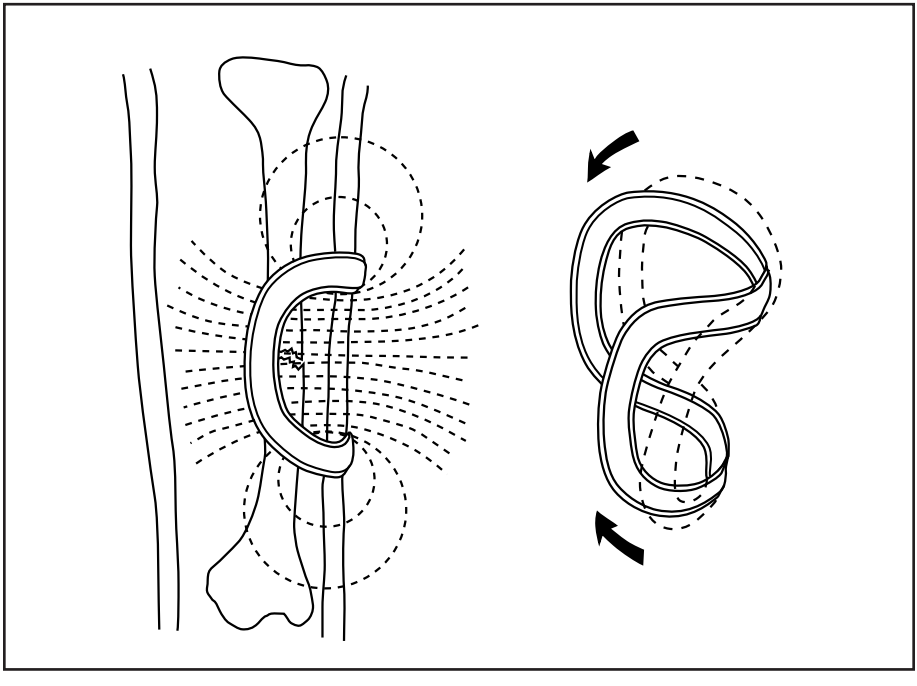
3) If the coil edge does not fall within the green zone, contact your Biomet representative for a suitable replacement and assistance.

Refer to pages 24-28 for diagrams of the Flexion Gauges.

CONFORMING THE FLX® COIL

The FLX® coil is easily conformable so it may be shaped to the surface anatomy of the fracture site being treated. The coil is also rigid enough to retain its shape once conformed. The lightweight, low, flat profile makes the coil easy to apply and more comfortable for the patient to wear.

The coil is designed to be bent in only one direction (single plane, see illustration). It should not be twisted or kinked.

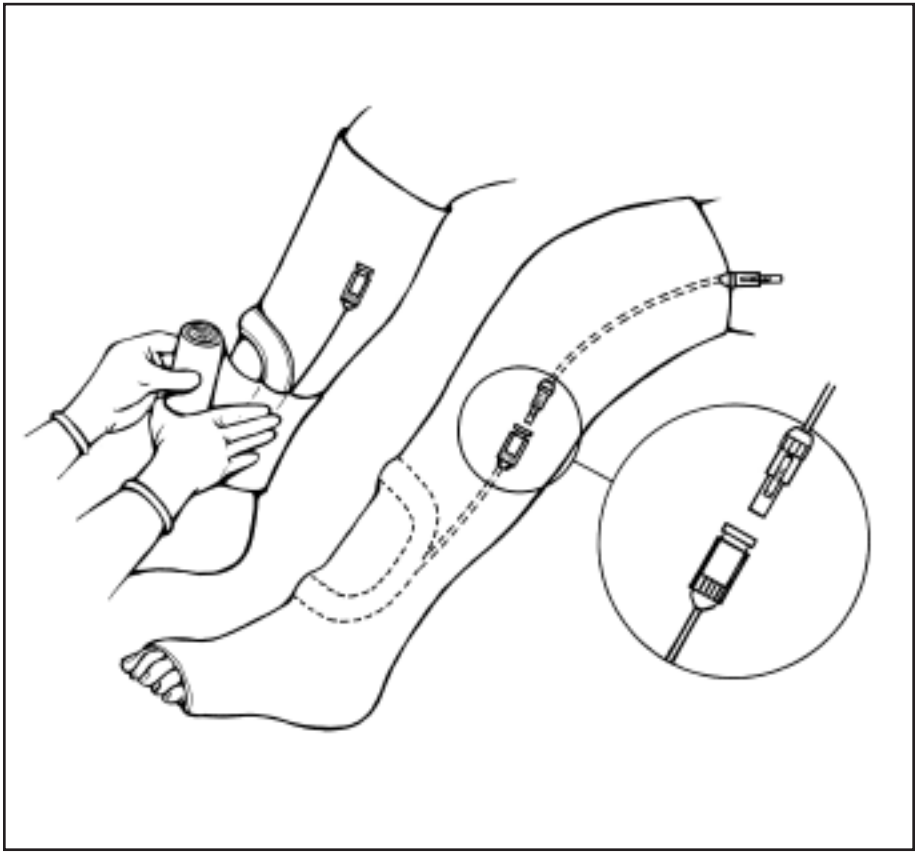


FLX® COIL APPLICATIONS

It is necessary that the entire fracture site receive a therapeutic pulsing field. This is accomplished by placing the treatment coil over the fracture site. Ensure that the entire fracture is centered within the treatment coil window. The coil is designed to permit routine follow-up examination by x-ray.

CASTED APPLICATIONS:

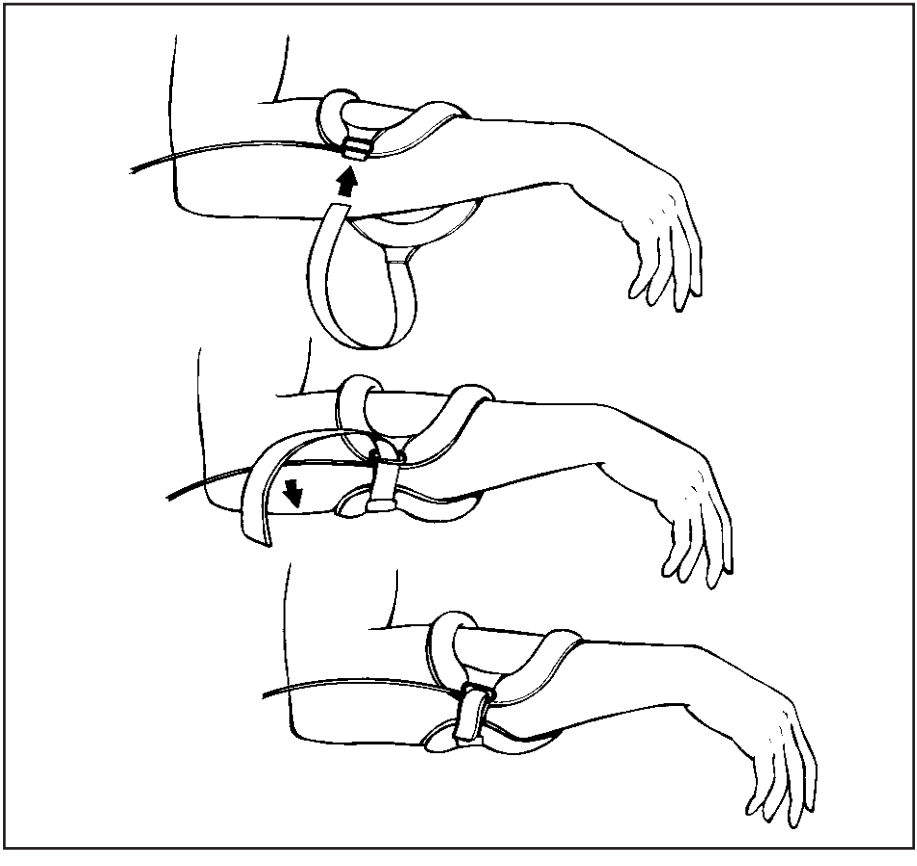
1. Apply 1-2 rolls of casting material (synthetic or plaster) in the usual manner and allow it to set. Center the coil over the fracture site, confirming correct placement with an x-ray if necessary.
2. Incorporate the coil into the cast with an additional wrap of casting material.
3. Position the connector mounting assembly near the coil and incorporate it into the cast with additional cast material.



SPECIAL NOTE: *If patient compliance with the system is not a concern, the treatment coil may be placed on top of a cast or brace. Be sure to mark the coil placement with an indelible marker for easy refitting by the patient.*

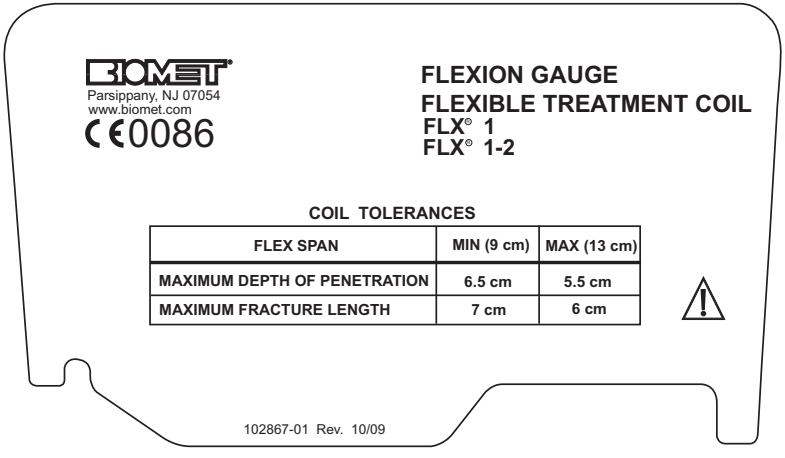
NONCASTED APPLICATIONS:

1. If using the coil directly on the skin, place the foam padding inside the coil.
2. Position the FLX® coil over the fracture site. The entire fracture site should be centered within the coil treatment window.
3. Attach and secure the FLX® coil around the extremity with the Velcro® strap or the garment to give the patient a snug yet comfortable fit.

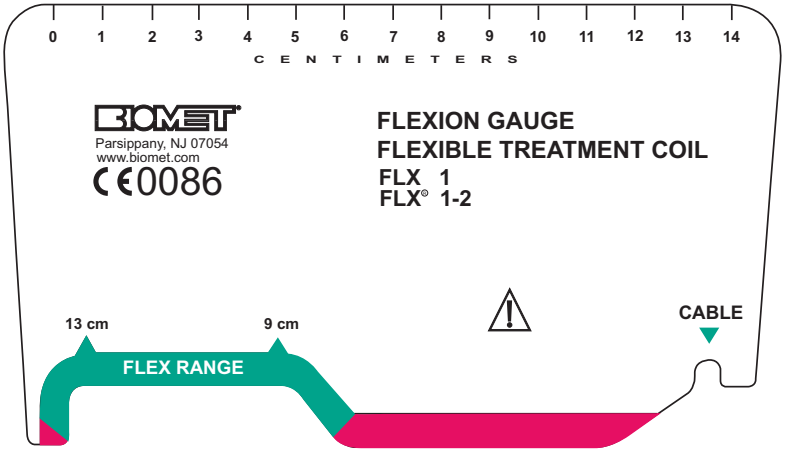


NOTE: *To allow flexibility in positioning, the treatment coil was designed with a large treatment window. However, it is recommended that the center of the coil be positioned over the fracture site.*

Front View

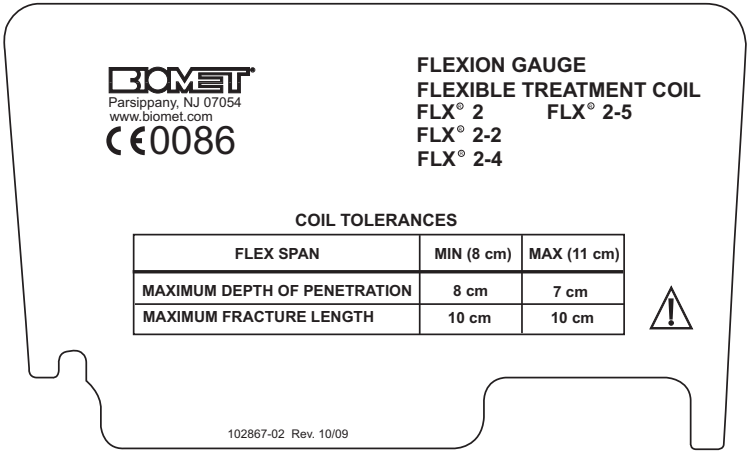


Back View

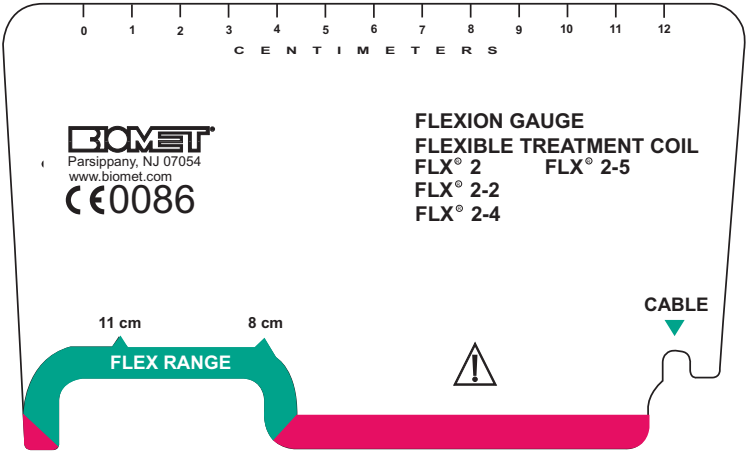


Not to scale

Front View

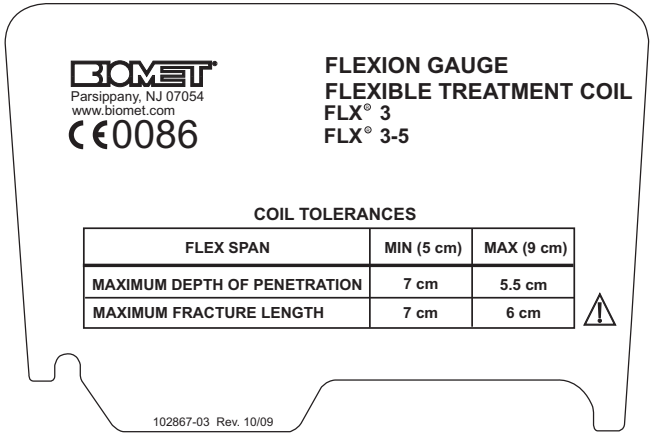


Back View

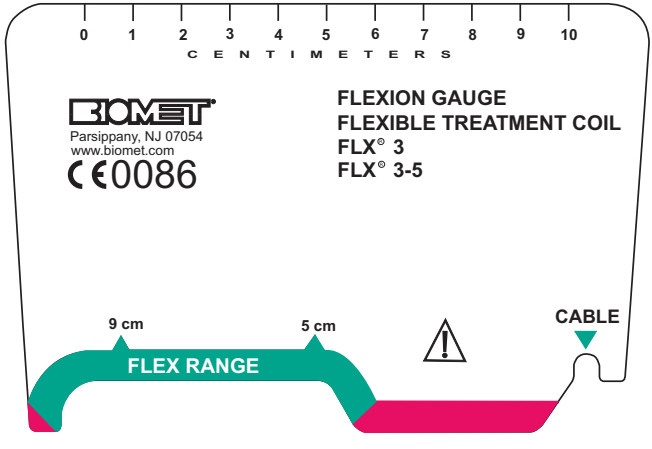


Not to scale

Front View

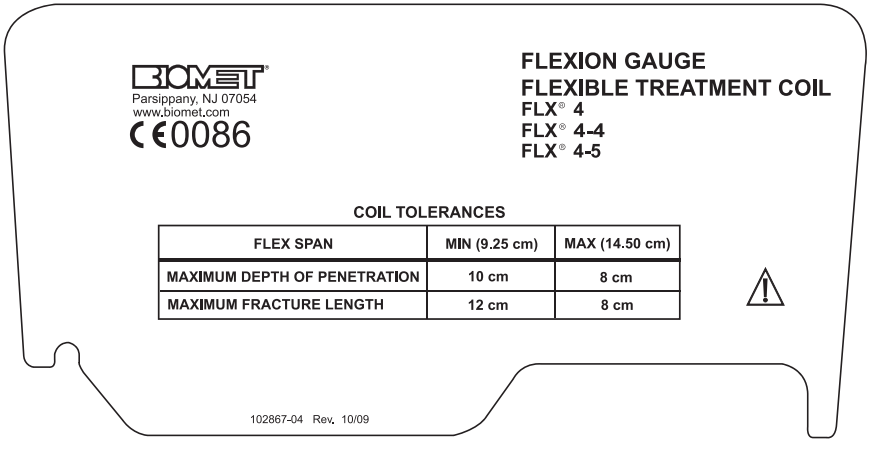


Back View

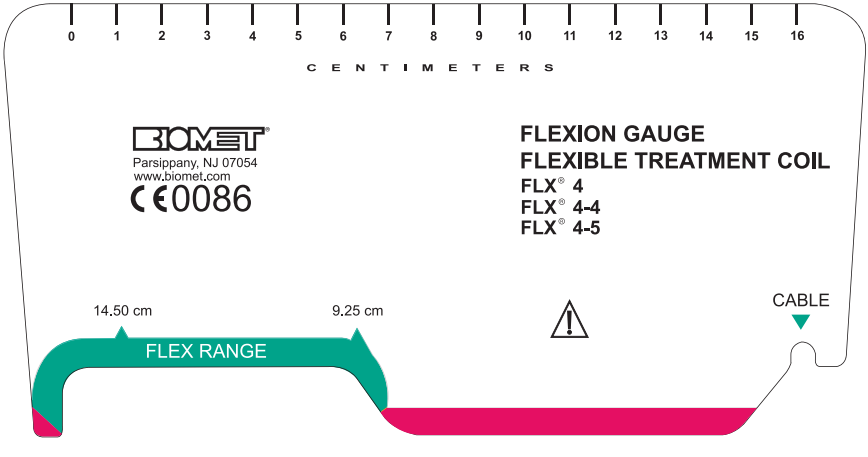


Not to scale

Front View

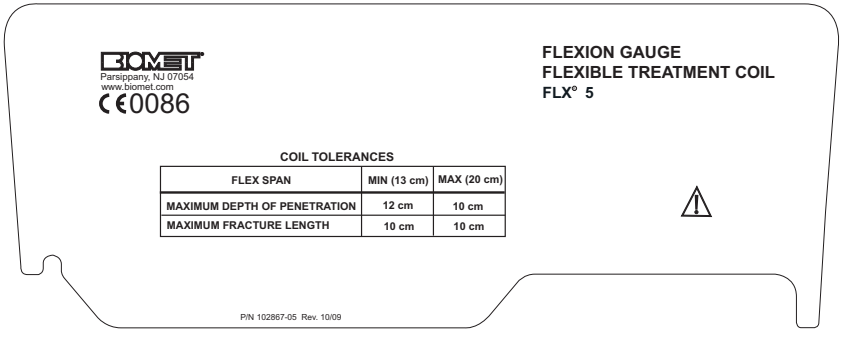


Back View

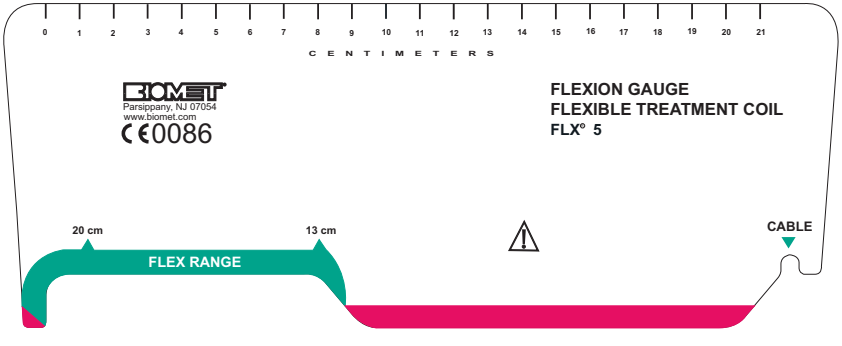


Not to scale

Front View



Back View



Not to scale

Coil Application Instructions

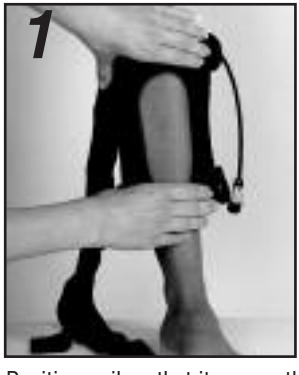
Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5111	FLX® 1-1	0101	Radius, Ulna, Malleolus (M/L)
5211	FLX® 2-1	0201	Tibia, Fibula, Radius, Ulna
5411	FLX® 4-1	0401	Humerus, Tibia, Fibula, Radius, Ulna,

FLX® 1-1 OR 2-1 OR 4-1 LONG VERTICAL FRACTURE APPLICATION

See Flexion Gauge Instructions for measuring the tolerances of the coil on page 31-33.

Used for long vertical fracture lengths: comminuted and segmented fracture applications.



Position coil so that it covers the entire fracture length, according to physician instructions (Position coil with cable toward waist). Make sure coil is firmly in place before securing straps.

Bring top and bottom straps around back to opposite side.

Press strap onto Velcro® hook. Readjust both straps for a secure, comfortable fit. DO NOT over tighten.

Cut excess straps to size.

Flexion Gauge Instructions for FLX® 1-1, FLX® 2-1 & FLX® 4-1 Coils

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be checked for the proper shape.

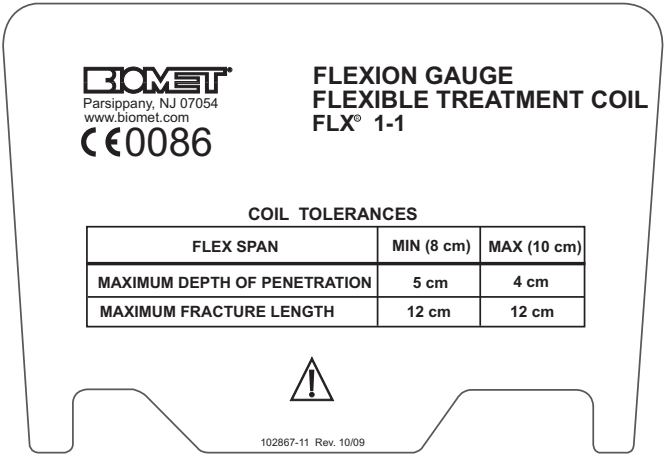
1) Place the coil at the treatment site and shape for best fit. Coil should be bent only in one direction. Do not kink or twist the coil.

2) Remove the shaped coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite coil edge should fall within the green zone in the area marked "FLEXION RANGE". Each Flexion Gauge has a chart of coil tolerances with depth of penetration data.

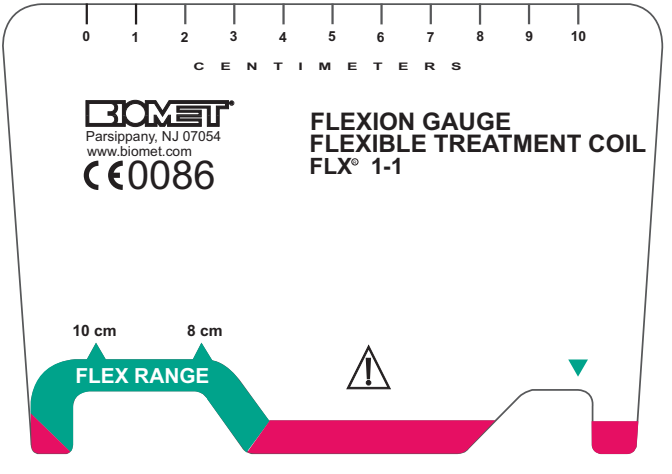
3) If the coil edge does not fall within the green zone, contact your Biomet representative for a suitable replacement and assistance.

Refer to pages 31-33 for diagrams of these Flexion Gauges.

Front View

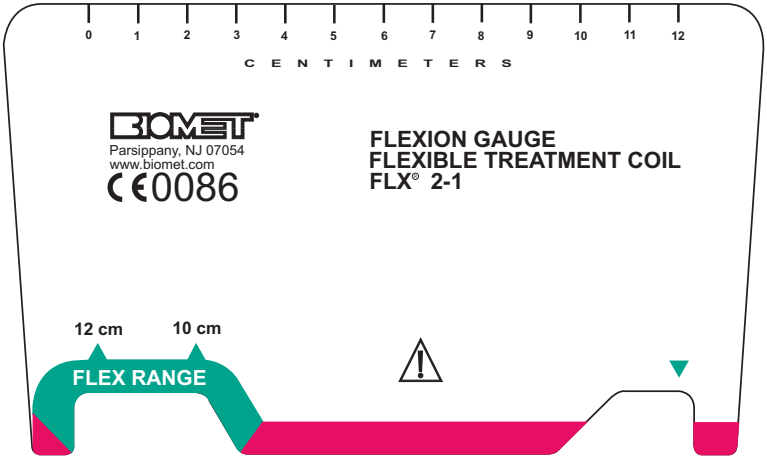


Back View

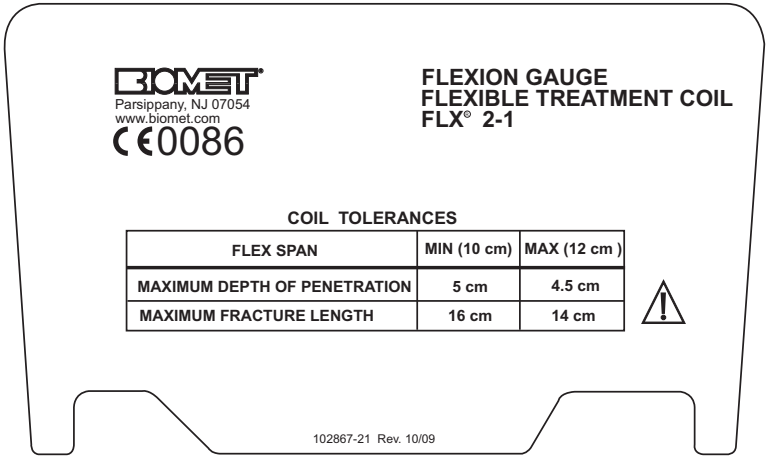


Not to scale

Front View



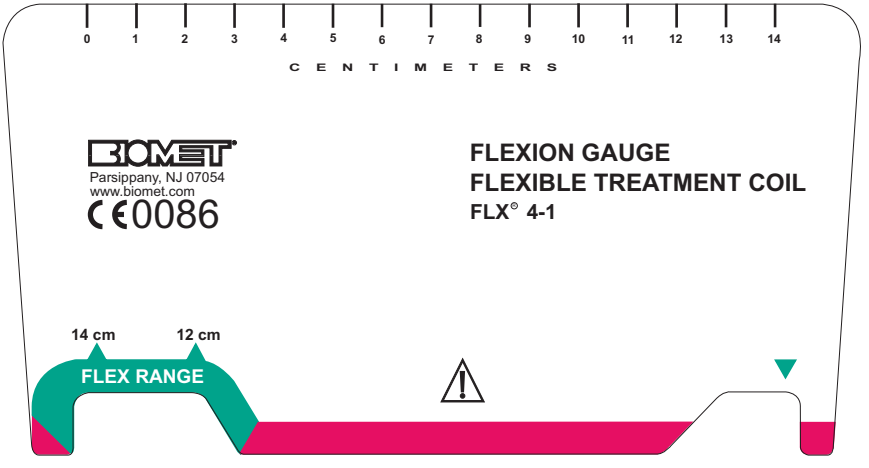
Back View



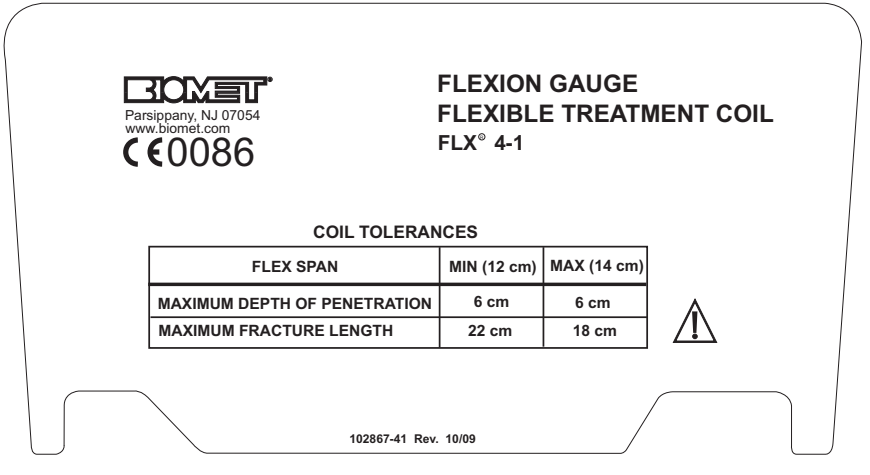
FLEX SPAN	MIN (10 cm)	MAX (12 cm)
MAXIMUM DEPTH OF PENETRATION	5 cm	4.5 cm
MAXIMUM FRACTURE LENGTH	16 cm	14 cm

Not to scale

Front View



Back View



FLEX SPAN	MIN (12 cm)	MAX (14 cm)
MAXIMUM DEPTH OF PENETRATION	6 cm	6 cm
MAXIMUM FRACTURE LENGTH	22 cm	18 cm

Not to scale

Coil Application Instructions

Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5112	FLX® 1-2	0102	Metatarsals, Cuniform Cuboid
5212	FLX® 2-2	0202	Metatarsals, Cuniform Cuboid

FLX® 1-2, 2-2 METATARSAL APPLICATION

See Flexion Gauge Instructions for measuring the tolerances of the coil on page 36-37.

Used for metatarsal fracture applications and may be applied over a foot shoe garment or bootie. The FLX® 1-2 and FLX® 2-2 treatment coils have a foam overlay on the exterior of the coil that permits a Velcro® patch face to open through the window in the treatment coil.

Conform the treatment coil to the metatarsal site.

Securely fasten the treatment coil by pressing on the back of the Velcro® patch within the center of the treatment coil. No trimming or readjusting is required.

Flexion Gauge Instructions for FLX® 1-2 & FLX® 2-2 Coils

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be checked for the proper shape.

1) Place the coil at the treatment site and shape for best fit. Coil should be bent only in one direction. Do not kink or twist the coil.

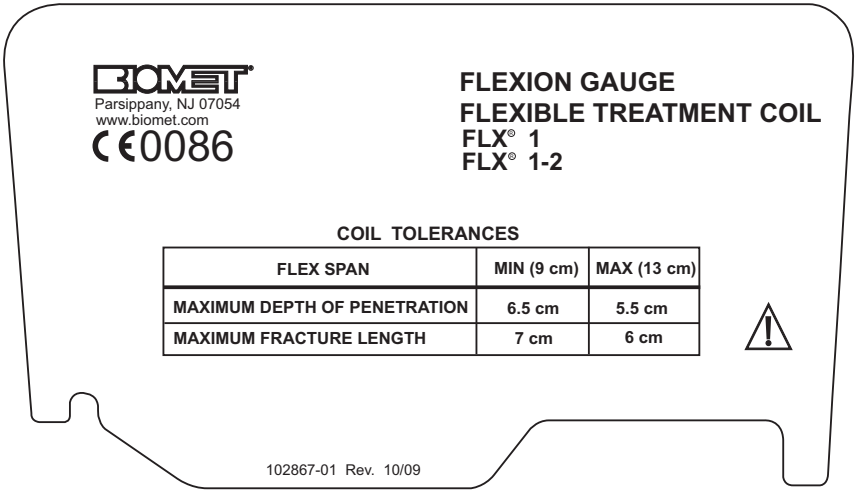
2) Remove the shaped coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite coil edge should fall within the green zone in the area marked "FLEXION RANGE". Each Flexion Gauge has a chart of coil tolerances with depth of penetration data.

3) After verifying the coil shape is within the green zone, affix the foam backing to the coil via the snaps at each corner. The Velcro® strap should be exposed through the coil window facing the treatment site.

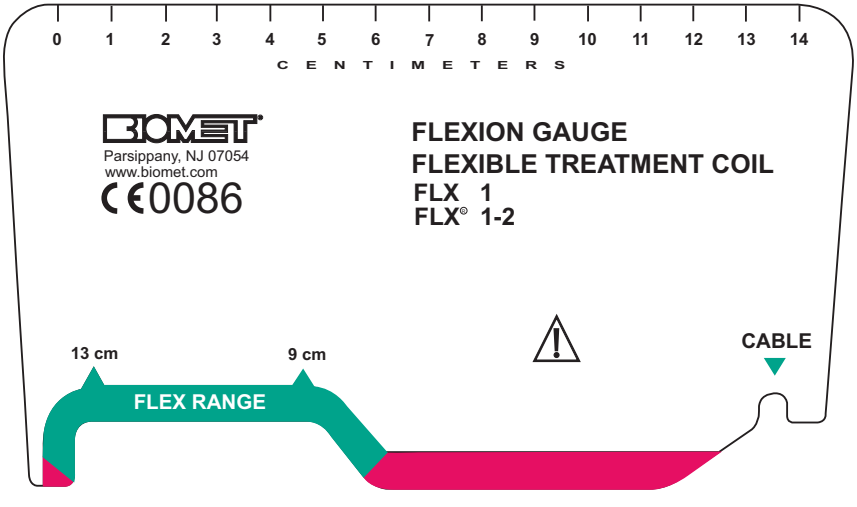
4) If the coil edge does not fall within the green zone, contact your Biomet representative for a suitable replacement and assistance.

Refer to pages 36 and 37 for diagrams of these Flexion Gauges.

Front View

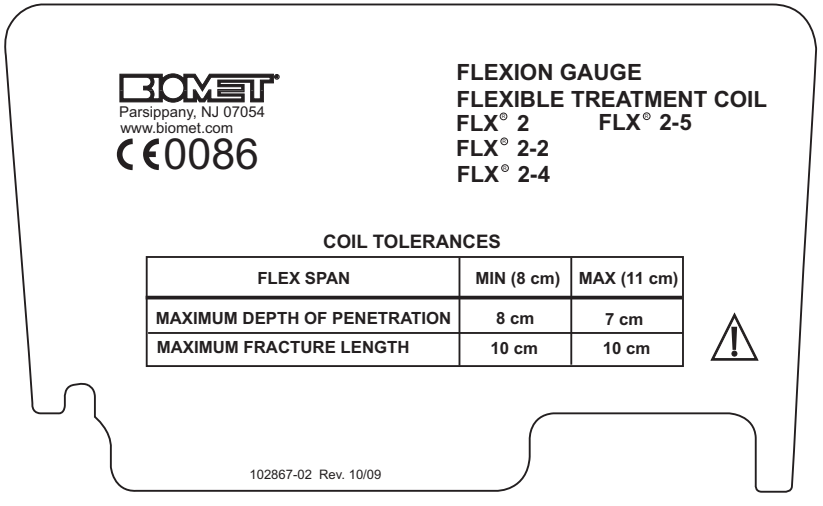


Back View

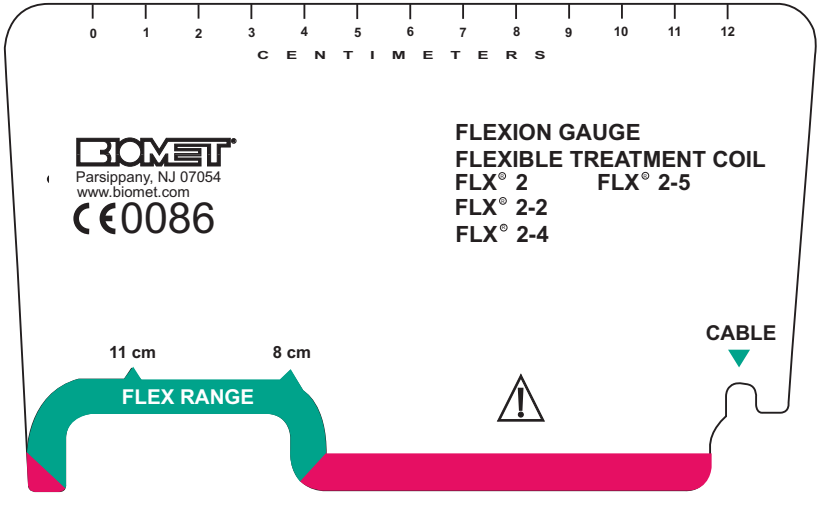


Not to scale

Front View



Back View



Not to scale

Coil Application Instructions

Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5113	FLX® 1-3	0103	Clavicle
5213	FLX® 2-3	0203	Clavicle - Larger

FLX® 1-3 OR 2-3 CLAVICLE APPLICATION

See Flexion Gauge Instructions for measuring the tolerances of the coil on pages 40-41. Used for right or left clavicle fracture applications.

NOTE: Coil comes pre-assembled for right clavicle applications only. For left clavicle applications, unsnap the two straps on the pre-assembled coil and switch them.

Position coil on clavicle over fracture site, according to physician instructions (Position coil with cable toward waist). Make sure coil is firmly in place before securing straps.

Bring long strap diagonally across the back and then around to the front across the chest. Press strap onto Velcro® hook. Dotted line represents alternate placement of long strap.

Short strap is then positioned under the arm and brought around to the front. Attach short strap to the coil by pressing strap onto Velcro® hook. Readjust both long and short straps for a secure, comfortable fit (DO NOT over tighten).

Cut excess straps to size.

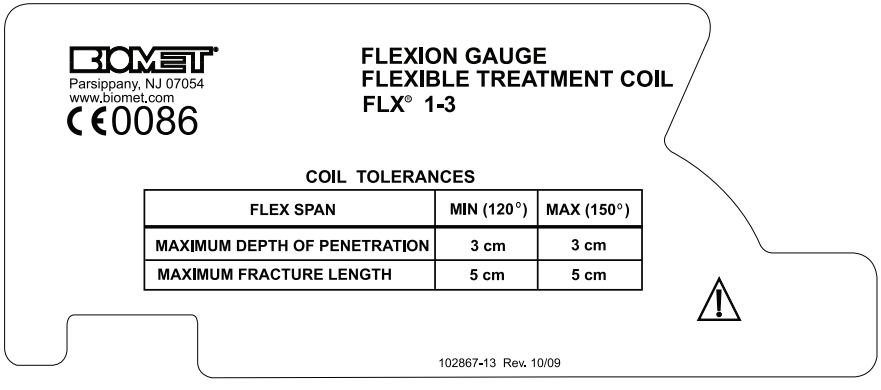
Flexion Gauge Instructions for FLX® 1-3 & FLX® 2-3 Coils

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be checked for the proper shape.

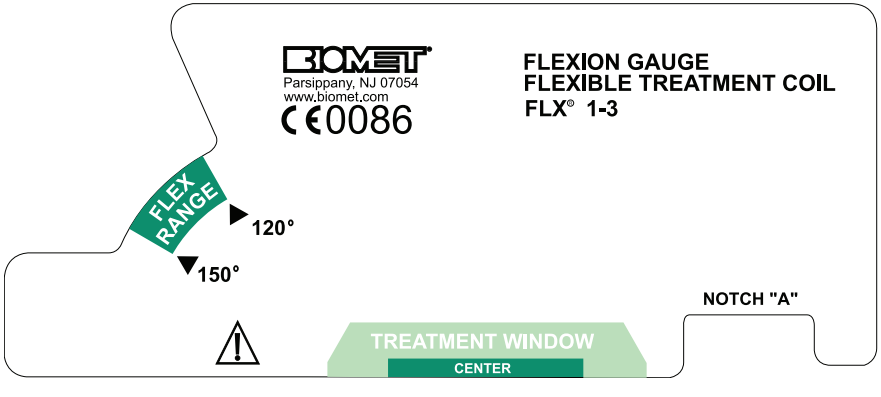
1) Place the coil at the treatment site and shape for best fit. Coil should be bent only in one direction. Do not kink or twist the coil.
2) Remove the shaped coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion gauge marked with a green triangle. Move the gauge through the open middle of the coil until the opposite coil edge touches the gauge again. The coil edge should fall within the green zone in the area marked “FLEX RANGE”. Each Flexion Gauge has a chart of coil tolerances with depth of penetration data.
3) If the coil edge does not fall within the green zone, contact your Biomet representative for a suitable replacement and assistance.

Refer to pages 40 and 41 for diagrams of these Flexion Gauges.

Front View



Back View



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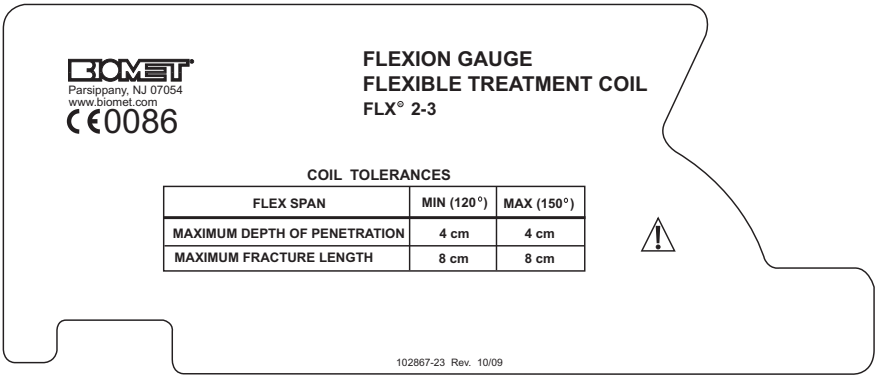
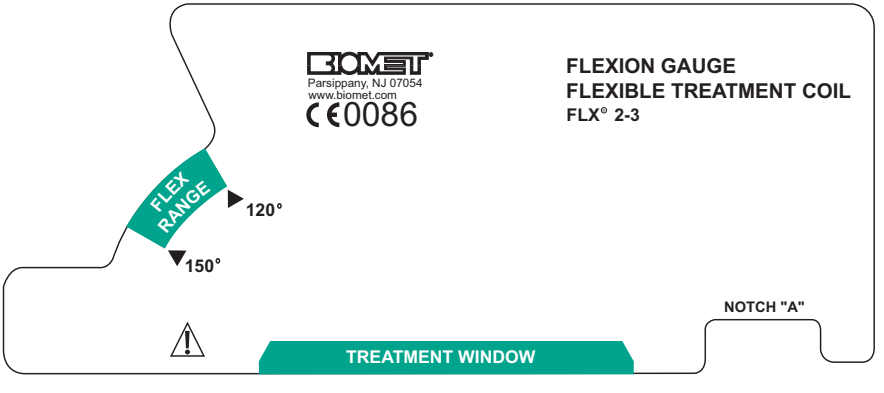
Front View



Back View



Not to scale

Coil Application Instructions for: FLX® 2-4 and FLX® 4-4 Coils

Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5214	FLX® 2-4	0204	Ankle
5414	FLX® 4-4	0404	Ankle - Larger

FLX® 2-4 AND 4-4 ANKLE/ELBOW APPLICATION

See Flexion Gauge Instructions for measuring the tolerances of the coil on page 44.

Used for ankle/elbow fracture applications.

NOTE: Position coil with cable toward waist.
Make sure coil is firmly in place before securing straps.

1

Position coil over the fracture site at the back of the ankle (for ankle application) or over the elbow (for elbow application), according to physician instructions. Make certain the coil is flush with the bottom of the foot or centered over the elbow. Make sure coil is firmly in place before securing straps.

2

Both top & bottom straps are then positioned over the front of the ankle or elbow.

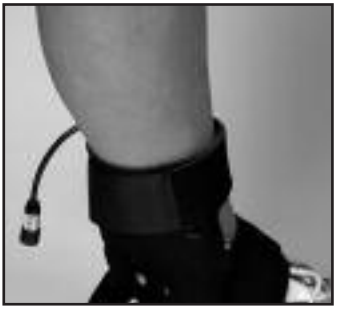
3

Fasten straps into place by pressing strap onto Velcro® hook.

4

Readjust both straps for a secure, comfortable fit opposite the Velcro® hook before cutting excess straps to size. DO NOT over tighten.

5



Optional (for ankle application only): If the coil migrates upward, you may use the additional strap provided to secure the coil. Simply fasten one end of the strap to the medial (inside seam) side of the ankle, bring strap under the foot and back around to the lateral side (outside) side of ankle. Fasten strap into place by pressing strap onto Velcro® hook.

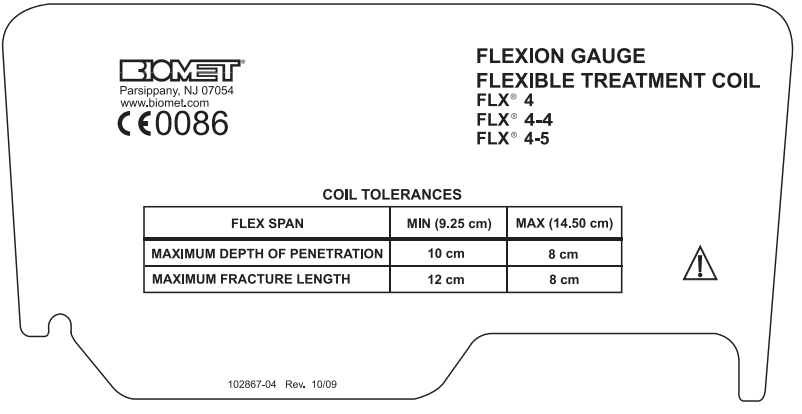
Flexion Gauge Instructions for FLX® 2-4 & FLX® 4-4 Coils

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be checked for the proper shape.

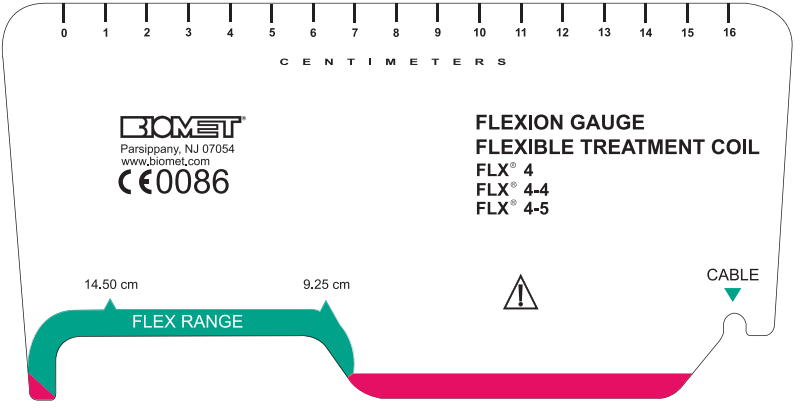
1) Place the coil at the treatment site and shape for best fit. Coil should be bent only in one direction. Do not kink or twist the coil.
2) Remove the shaped coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite coil edge should fall within the green zone in the area marked "FLEXION RANGE". Each Flexion Gauge has a chart of coil tolerances with depth of penetration data.
3) If the coil edge does not fall within the green zone, contact your Biomet representative for a suitable replacement and assistance.

Refer to page 45 for a diagram of the FLX® 4-4 Coil Flexion Gauge.
Refer to page 25 for a diagram of the FLX® 2-4 Coil Flexion Gauge.

Front View



Back View



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Coil Application Instructions For: FLX® 2-5, 3-5, 4-5

Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5215	FLX® 2-5	0205	Humerus, Proximal - Small
5315	FLX® 3-5	0305	Humerus, Proximal - Medium
5415	FLX® 4-5	0405	Humerus, Proximal - Larger

FLX® 2-5 OR 3-5 OR 4-5 PROXIMAL HUMERUS/SHOULDER APPLICATION

See Flexion Gauge Instructions for measuring the tolerances of the coil on page 47.

Used for proximal humerus/shoulder applications.

Position coil over the proximal humerus fracture site, according to physician instructions (Position coil with cable toward waist). Make sure coil is firmly in place before securing straps.

Bring the long strap diagonally across the back and then around to the front across the chest. Press strap onto Velcro® hook.

Second strap is then positioned under the arm and brought around to the front. Attach strap to the coil by pressing strap onto Velcro® hook.

Readjust both straps for a secure, comfortable fit. DO NOT over tighten before cutting excess straps to size.

Flexion Gauge Instructions for FLX® 2-5, FLX® 3-5 & FLX® 4-5 Coils

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be checked for the proper shape.

1) Place the coil at the treatment site and shape for best fit. Coil should be bent only in one direction. Do not kink or twist the coil.
2) Remove the shaped coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite coil edge should fall within the green zone in the area marked "FLEXION RANGE". Each Flexion Gauge has a chart of coil tolerances with depth of penetration data.
3) If the coil edge does not fall within the green zone, contact your Biomet representative for a suitable replacement and assistance.

Refer to pages 37, 48 and 49 for Flexion Gauge diagrams.

Front View

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Parsippany, NJ 07054
www.biomet.com
CE 0086

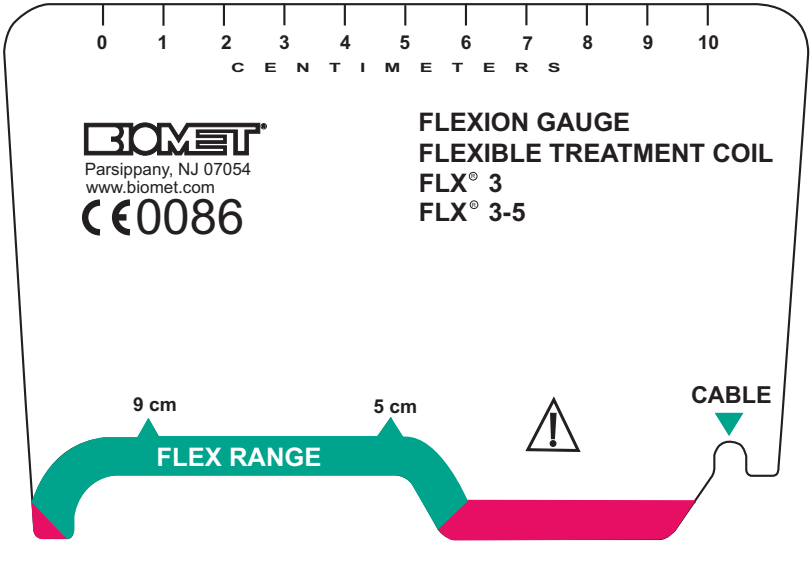
FLEXION GAUGE
FLEXIBLE TREATMENT COIL
FLX® 3
FLX® 3-5

COIL TOLERANCES

FLEX SPAN	MIN (5 cm)	MAX (9 cm)
MAXIMUM DEPTH OF PENETRATION	7 cm	5.5 cm
MAXIMUM FRACTURE LENGTH	7 cm	6 cm

102867-03 Rev. 10/09

Back View



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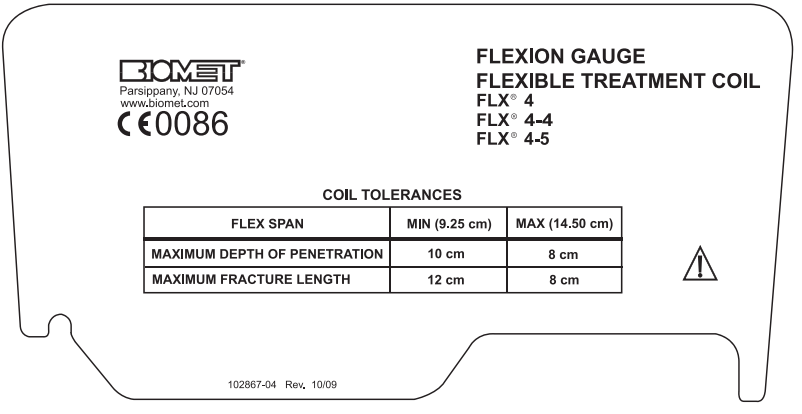
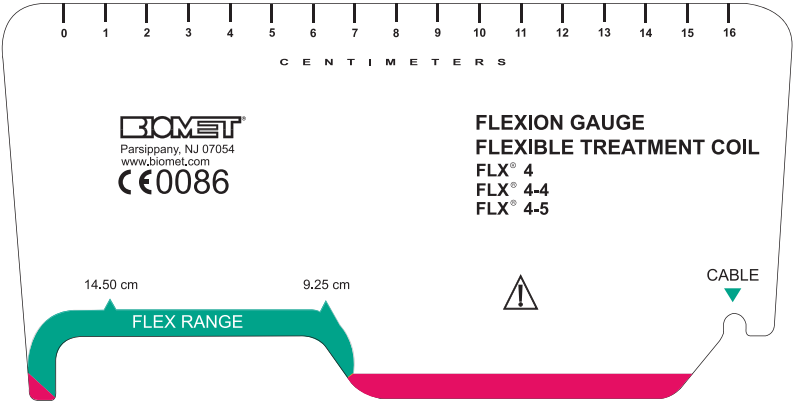
Front View



Back View



Not to scale

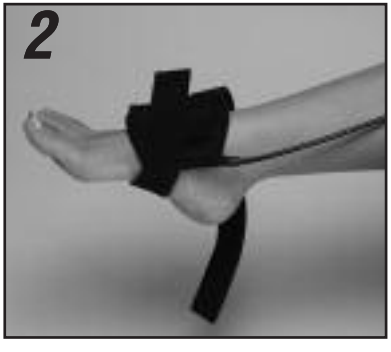
Coil Application Instructions For: FLX® - XL Coilette

Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5620	FLX® - XL Coilette	5700	Foot/Ankle, Hand, Wrist

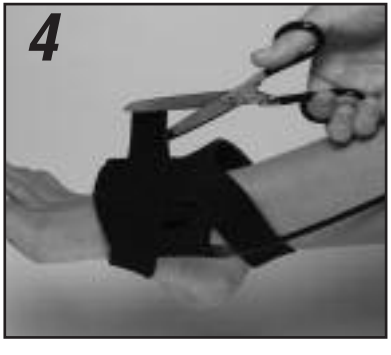
ANKLE APPLICATION

Center the coil over the fracture site. Conform the coil and verify with gauge.



Wrap lower strap around bottom of foot and attach to Velcro® hook.

Wrap upper strap around ankle and cable. Attach to Velcro® hook.



Adjust straps for comfort. Excess strap length may be cut away. When treatment is complete for the day, remove the coilette by loosening the straps.

Coil Application Instructions For: FLX® - XL Coilette

Applies to:

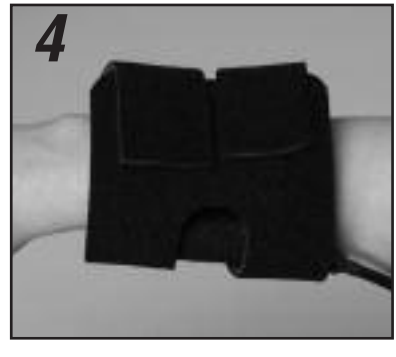
Assembly #	Description	Coil Replacement #	Suggested Placement
5620	FLX® - XL Coilette	5700	Foot/Ankle, Hand, Wrist

WRIST APPLICATION

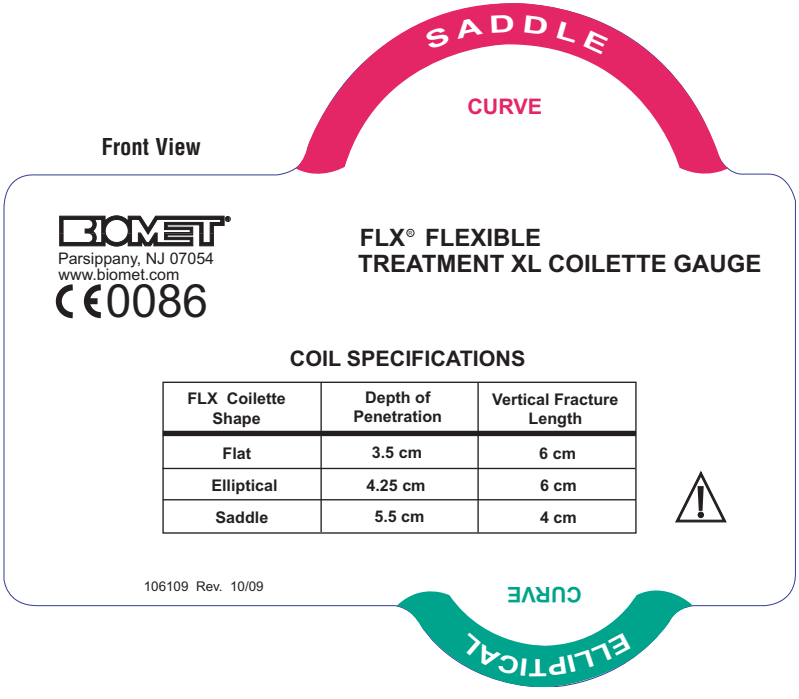
Center the coilette over the fracture site. Conform shape and remove. Verify coil is conformed within treatment limit with Flexion gauge.

Secure upper proximal strap first. Wrap strap around hand and attach to Velcro® hook.

Secure lower/distal strap by wrapping around fracture site and attaching to Velcro® hook. Cut away excess strap length.



Adjust straps for comfort. When treatment is complete for the day, remove the coilette by loosening the straps.


SADDLE
CURVE
Front View
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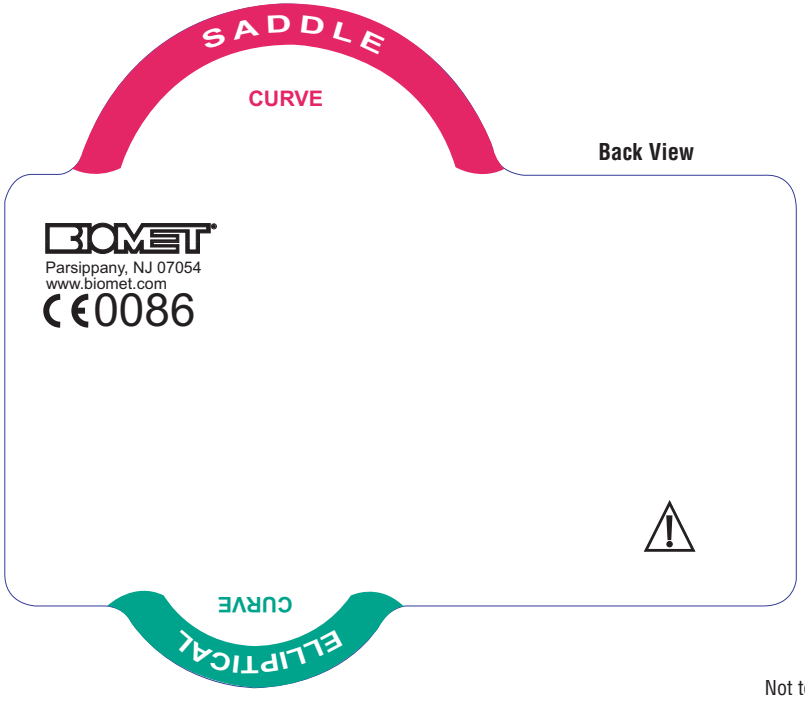
CE 0086
FLX® FLEXIBLE
TREATMENT XL COILETTE GAUGE
COIL SPECIFICATIONS
FLX Coilette Shape | Depth of Penetration | Vertical Fracture Length
Flat | 3.5 cm | 6 cm
Elliptical | 4.25 cm | 6 cm
Saddle | 5.5 cm | 4 cm
106109 Rev. 10/09
CURVE
ELLIPTICAL


SADDLE
CURVE
Back View
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CE 0086
CURVE
ELLIPTICAL

Not to scale

Coil Application Instructions

Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5613	FLX® - Coilette Clavicle	0603	Clavicle

CLAVICLE PLACEMENT APPLICATION INSTRUCTIONS

See Conforming the Coil and Flexion gauge instructions on page 55.

Components: The FLX® Coilette Clavicle comes with a FLX® Coilette and straps to be fitted over the effected torso and shoulder.

1

Place the coilette and straps provided on a flat surface. The straps are provided snapped together. Notice that the strap with Velcro® is longer than the one without Velcro®.

2

a) Wrap the long strap with Velcro® around your chest and back onto itself. Secure it in place with the Velcro®

b) Note: The snap should be located in the center of your back.

3

Pull the remaining short strap from behind your back over the shoulder on the treatment side.

4

Place the FLX®-Coilette over the treatment site as instructed by your physician or Biomet representative.

5

Secure the Coilette in place by passing the strap over the Velcro® on the Coilette and onto the chest strap. Close the chest strap.

6a

a) Adjust for comfort. Excess shoulder and chest strap lengths may be then cut away.

6b

b) Common position.

7

When treatment is completed for the day, remove the coil by unhooking the strap from around your chest. Leave the strap over your shoulder secured to the coil and chest strap. Remove the coil. It is ready for your next daily treatment.

Flexion Gauge Instructions for FLX® Flexible Treatment Coilette -Clavicle

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be checked for the proper shape.

1) Place the coil at the treatment site and shape for best fit. The FLX® Coil must only be bent in one of two directions (Long or short axis, see illustrations that follow). Do not kink or twist the coil. The shape of the coil will determine the specifications.
2) Remove the shaped coil and utilize the Flexion Gauge to verify the acceptable bend according to the shape listed below.
3) If the coil edge does not fall within the green zone, contact your Biomet representative for a suitable replacement and assistance.

Optional Shapes
Flat – Flexion Gauge not required
Elliptical – Place treatment coil over green portion of Flexion Gauge. The treatment coil bend should not exceed the curve indicated on this Gauge.
Saddle – Place the treatment coil over the red portion of the Flexion Gauge. The coil bend should not exceed the curve indicated on this Flexion Gauge.

Refer to page 63 for a diagram of the Flexion Gauge.

Coil Application Instructions for the: FLX®-Mini

Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5630	FLX®-Mini	5650	Phalanges

Flexion Gauge Instructions for FLX®-Mini Coil

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be checked for the proper shape.

1) Place the coil at the treatment site and shape for best fit. Treatment coil should be bent only in one direction. Do not kink or twist the coil.
2) Remove the shaped treatment coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite treatment coil edge should fall within the green zone in the area marked “FLEX RANGE”. Each Flexion Gauge has a chart of coil tolerances with depth of penetration data.
3) If the treatment coil edge does not fall within the green zone, contact your Biomet representative for a suitable replacement and assistance.

Refer to page 58 for a diagram of the Flexion Gauge.

EBI Bone Healing System® FLX®-Mini Coilette Instructions

Slip wrist connector strap around wrist.

Adjust strap up or down arm until length of wire to FLX®-Mini Coilette is properly placed.

Feeding strap through ring, adjust and tighten securing strap to Velcro® hook.

b) Trim excess strap with scissors.

Adjust FLX®-Mini Coilette to size by squeezing or opening.

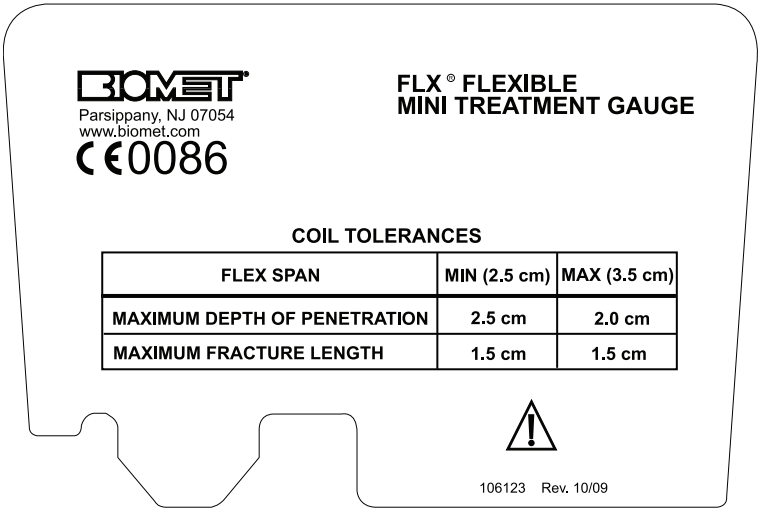
Secure FLX®-Mini Coilette in place by wrapping strap around finger and securing onto Velcro® hook.

Trim excess strap with scissors.

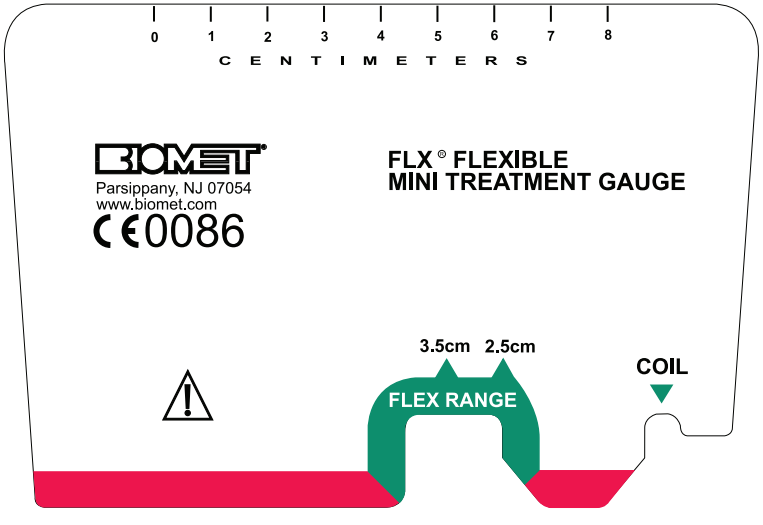
Warning! Do not place FLX®-Mini Coilette over metallic splints or jewelry.

Connect EBI Bone Healing System® Stimulator link cable to wrist connector by inserting plug into jack. Begin treatment.

Front View



Back View



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Coil Application Instructions for the: FLX®-Standard Coilette

Applies to:

Assembly #	Description	Coil Replacement #	Suggested Placement
5610	Standard Coilette	0600	Metatarsals, Scaphoid, Distal Radius, Cuboid, M-L Malleous

Flexion Gauge Instructions for FLX® Standard Coilette

In order to ensure proper fit and efficacious treatment, the Flexion Gauge should be checked for the proper shape.

1) Place the treatment coil at the treatment site and shape for best fit. The treatment coil must only be bent in one of two directions (Long or short axis, see illustrations that follow). Do not kink or twist the treatment coil. The shape of the treatment coil will determine the specifications.
2) Remove the shaped treatment coil and utilize the Flexion Gauge to verify the acceptable bend according to the shape listed below.
3) If the treatment coil edge does not fall within the green zone, contact your Biomet representative for a suitable replacement and assistance.

Optional Shapes

Flat - Flexion Gauge not required

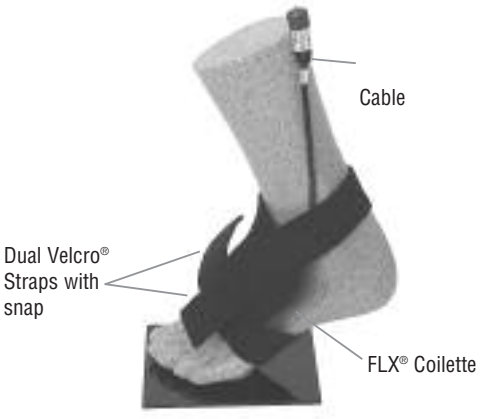
Elliptical - Place treatment coil over green portion of Flexion Gauge. The coil bend should not exceed the curve indicated on this Flexion Gauge.

Saddle - Place the treatment coil over the red portion of the Flexion Gauge. The coil bend should not exceed the curve indicated on this Flexion Gauge.

FLX®-STANDARD COILETTE FLEXIBLE TREATMENT COIL

Foot Application

For System Assembly #5610
and Coilette #0600



Attach the FLX®-Standard Coilette to the strap by connecting it to the Velcro® hook provided on the strap.

Center the FLX®-Standard Coilette over the fracture site.

Wrap lower strap around bottom of foot and attach to Velcro® hook.

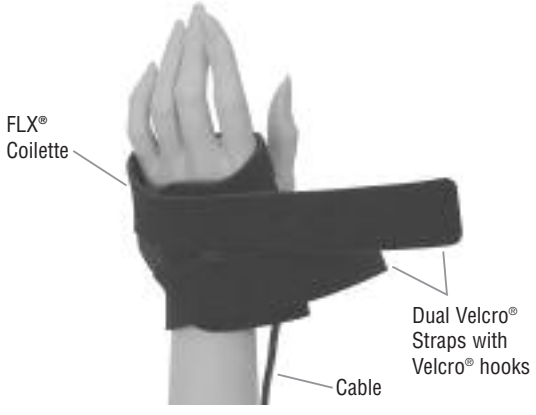
Wrap top strap around ankle and cable and attach to Velcro® hook.

Adjust strap for comfort.
Excess strap length may then be cut away.
When treatment is completed for the day, remove the FLX®-Standard Coilette by loosening the straps. Leave the straps attached to the Coilette. It is ready for your next daily treatment.

FLX®-STANDARD COILETTE FLEXIBLE TREATMENT COIL

Hand Application

For System Assembly #5610
and Coilette #0600



Shape and place the FLX®-Standard Coilette over the treatment site as instructed by your physician or Biomet representative.

Place the FLX®-Standard Coilette onto the Velcro® hook on the strap.

Place the FLX®-Standard Coilette over treatment site and bring straps around each side of thumb.

Secure Velcro® straps onto the Velcro® hook. Adjust for comfort.

Excess strap length may then be cut away.

When treatment is completed for the day, remove the FLX®-Standard Coilette by loosening the straps. Leave the straps attached to the FLX®-Standard Coilette. It is ready for your next daily treatment.

Biomet® FLX® Flexible Treatment Coilette

Specifications and Gauge Directions

FLX® Coilette Shape	Depth of Penetration	Vertical Fracture Length
Flat	2.75 cm	4 cm
Elliptical	3.5 cm	4 cm
Saddle	3.5 cm	2 cm

To insure efficacious treatment with the FLX® Coilette Coil:

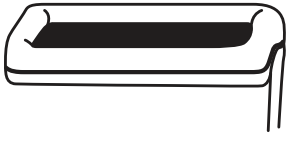
1. Place the Coilette on the treatment site and shape for best fit. The Coilette must only be bent in one of two directions (long axis or short axis, see illustrations). Do not kink or twist the Coilette.

2. The shape of the Coilette will determine the coil specifications (see above).

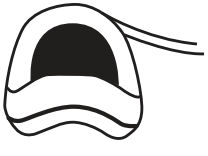
3. Remove the Coilette and utilize the enclosed FLX® Coilette Gauge to verify the shape listed below.

Optional Shapes:

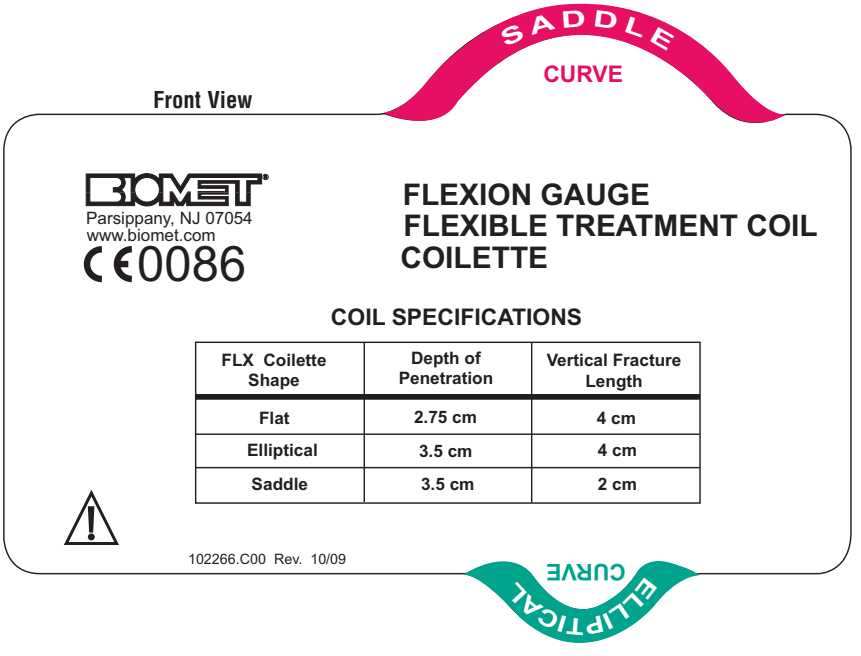
Flat Shape (see coil specifications above)
The FLX® Coilette Gauge is not needed.

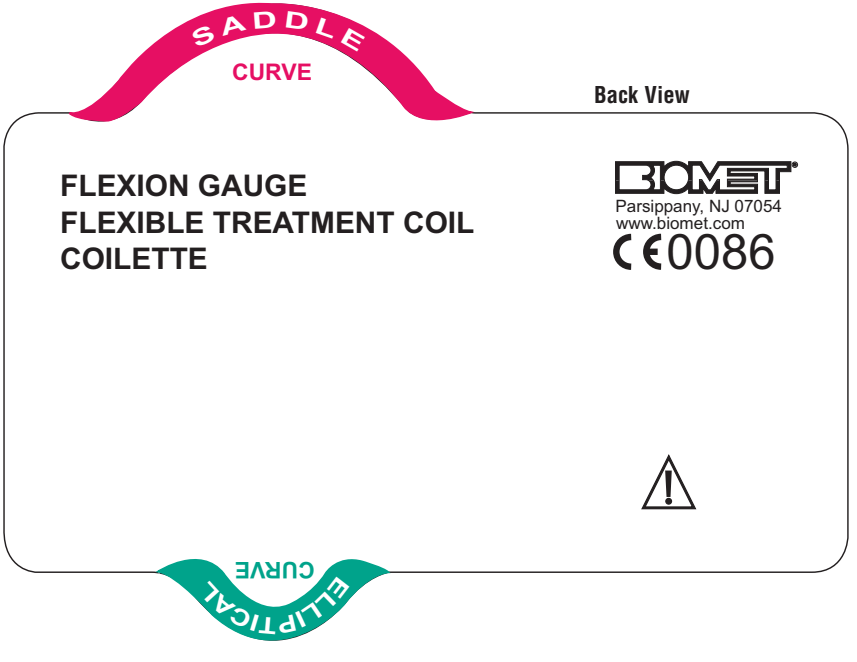


Elliptical Shape (see coil specifications above)
Place the Coilette over the green portion of the gauge marked “elliptical”. The Coilette bend should not exceed the elliptical curve indicated on the FLX® Coilette Gauge.



Saddle Shape (see specifications above)
Place the Coilette over the red portion of the gauge marked “saddle”. The Coilette bend should not exceed the saddle curve on the FLX® Coilette Gauge.


SADDLE
CURVE
Front View
BIOMET
Parsippany, NJ 07054
www.biomet.com
CE 0086
FLEXION GAUGE
FLEXIBLE TREATMENT COIL
COILETTE
COIL SPECIFICATIONS
FLX Coilette Shape
Depth of Penetration
Vertical Fracture Length
Flat
2.75 cm
4 cm
Elliptical
3.5 cm
4 cm
Saddle
3.5 cm
2 cm
102266.C00 Rev. 10/09
ELLIPTICAL CURVE


SADDLE
CURVE
Back View
FLEXION GAUGE
FLEXIBLE TREATMENT COIL
COILETTE
BIOMET
Parsippany, NJ 07054
www.biomet.com
CE 0086
ELLIPTICAL CURVE

Not to scale

CLEANING INSTRUCTIONS

THE 2001 SYSTEM
The controller and charger can be cleaned by wiping with a damp cloth and mild soap. Do not immerse in water or use solvents or other cleaning agents. Do not machine dry.

FLX® COILS
FLX® coils are not sterile. Clean with mild soap and water by wiping with a damp cloth. Do not immerse in water or any liquid.

TREATMENT COMPLETION

Treatment should not be suspended until healing occurs or your physician recommends that you discontinue use of the device. The device is programmed to deliver 400 consecutive days of treatment.

The maximum recommended treatment period is 9 months. See "SYSTEM ENDPOINT 400 DAYS" (Page 17).

RETURNING DEFECTIVE PRODUCT

A Stimulator Control Unit, AC Adapter, Flexible Treatment Coil, or Link Cable that is defective may be returned to Biomet. To return a part, or if you are having difficulty with the operation of your EBI Bone Healing System® Stimulator, please contact the Quality Assurance Department:

1-973-299-9300 (follow prompts to Product Support)

NOTE: Only defective units may be returned to Biomet. Units that have passed through their system endpoints or that have previously delivered a complete prescribed treatment must be disposed of properly (see Disposal Instructions).

DISPOSAL INSTRUCTIONS

The Stimulator control unit, AC adapter, link cables, FLX® Treatment Coil, cradle and battery are regulated and should be properly disposed of or recycled according to local statutes and regulations. Please contact your local recycling center for instructions and procedures to safely dispose of the EBI Bone Healing System® Stimulator.

EQUIPMENT CLASSIFICATION

- Models 2001, 2001A, 2001J, 2001U
  Class I
  Type B
- Models 2001E
  Class II
  Type B
- Ordinary equipment without protection against ingress of water
- Equipment not suitable for use in presence of flammable anaesthetic mixture with air or with oxygen or with nitrous oxide
- Mode of operation – continuous

SYMBOL DESCRIPTION


Type B


Manufacturer


Direct Current

Catalog Number


Alternating Current

Serial Number


Attention - See Instructions


Non-ionizing Radiation


Class II


Single Patient Use/
Prescription Only


Not for use by patients who are pregnant or becoming pregnant


Not recommended for patients with certain types of pacemakers or implantable defibrillators

Transportation and storage temperature range


WEEE - Do not discard with household waste

ORDERING INFORMATION

To order replacement coils or related components simply contact your Biomet representative or call the Biomet Patient Support Department directly at 1-800-526-2579, 8:30 a.m. to 6:30 p.m. Eastern Time Monday through Friday. Outside the United States contact your local EBI/Biomet Distributor, or call 1-973-299-9300.

The following information is necessary to expedite any requests:

- Patient name
- Physician name
- Where to send replacement items (patient home, MD office, etc.)
- Available component parts (See following page)

REFERENCES

C.A.L. Bassett, Robert J. Pawluk, and A.A. Pilla. "Augmentation and Bone Repair by Inductively Coupled Electromagnetic Fields". Science 184:575-577, 1974.

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C.A.L. Bassett, S.N. Mitchell, and S.R. Gaston. "Treatment of Ununited Tibial Diaphyseal Fractures With Pulsing Electromagnetic Fields". Journal of Bone and Joint Surgery Vol. 63-A, No. 4, pp. 511-523, April, 1981.

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C.A.L. Bassett, Pulsing Electromagnetic Fields: "A New Method to Modify Cell Behavior in Calcified and Non-Calcified Tissue". Calcified Tissue, Int. Vol. 34, No. 1:1-8, 1982.

Model 2001 BHS Replacement components
Applies to:

Description	Part Number
Coil - FLX® 1	0100
Coil - FLX® 1-1	0101
Coil - FLX® 1-2	0102
Coil - FLX® 1-3	0103
Coil - FLX® 2	0200
Coil - FLX® 2-1	0201
Coil - FLX® 2-2	0202
Coil - FLX® 2-3	0203
Coil - FLX® 2-4	0204
Coil - FLX® 2-5	0205
Coil - FLX® 3	0300
Coil - FLX® 3-5	0305
Coil - FLX® 4	0400
Coil - FLX® 4-1	0401
Coil - FLX® 4-4	0404
Coil - FLX® 4-5	0405
Coil - FLX® 5	5500
Coil - Standard Coilette	0600
Coil - Clavicle Coilette	0603
Coil - Mini-Coilette	5650
Coil - XL	5700
Controller	1067223-00
Charging Cradle	1067223-01

ELECTROMAGNETIC COMPATIBILITY

- The use of accessories and cables other than those supplied may result in increased emissions or decreased immunity of the equipment or system
- This equipment should not be used adjacent to or stacked upon other equipment
- Portable and mobile RF communications equipment can adversely affect the operation of Medical Electrical Equipment
- In the event this equipment interferes with the operation of other equipment, or experiences interference from other equipment, to continue treatment it will be necessary to move the Model 2001 Bone Healing System away from the source of the interference as indicated in table 4

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions

The Model 2001 Bone Healing System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2001 Bone Healing System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The Model 2001 Bone Healing System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Model 2001 Bone Healing System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity

The Model 2001 Bone Healing System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2001 Bone Healing System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 610004-2	± 6 kV contact ± 8 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV for differential mode ± 2 kV for common mode		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 2001 Bone Healing System requires continued operation during power mains interruptions, it is recommended that the Model 2001 Bone Healing System be powered from an uninterruptible power supply (UPS).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity

The Model 2001 Bone Healing System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 2001 Bone Healing System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 2001 Bone Healing System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms	1 Vrms	$d = 3.5 \sqrt{P}$ $d = 3.5 \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	1 V/m	$d = 7 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1. At 80 MHz and 800 MHz, the higher frequency applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 2001 Bone Healing System is used exceeds the applicable RF compliance level, the Model 2001 Bone Healing System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model 2001 Bone Healing System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Model 2001 Bone Healing System

The Model 2001 Bone Healing System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 2001 Bone Healing System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile communications equipment (transmitters) and the Model 2001 Bone Healing System as recommended below, according to the maximum power output of the communications equipment.

Rated maximum output power of transmitter	**Separation distance (meters) according to frequency of transmitter**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
W	$d = 3.5 \sqrt{P}$	$d = 3.5 \sqrt{P}$	$d = 7 \sqrt{P}$
.01	.35	.35	.7
.1	1.1	1.1	2.21
1	3.5	3.5	7
10	11.06	11.06	22.13
100	35	35	70

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

QUESTIONS AND ANSWERS

This section has been prepared to answer some of the questions most frequently asked about the EBI Bone Healing System® Stimulator. If you have any further questions after reading it, please contact your doctor or call Biomet's Patient Support Department at 1-800-526-2579 8:30 a.m. – 6:30 p.m. Eastern Time Monday through Friday. Outside the United States contact your local EBI/Biomet Distributor, or call 1-973-299-9300.

Bone is one of the tissues of the human body with the ability to mend itself when injured, in much the same way as skin and other tissues can. After a break, bone repair processes usually assure a sound union within a few months. Occasionally, however, the formation of new bone is slow and the break fails to heal properly. Medically, prescribed use of the EBI Bone Healing System® Stimulator, by a physician, can often promote healthy bone growth and repair in cases when normal healing does not appear satisfactory.

Some commonly asked questions about the EBI Bone Healing System® Stimulator

1. **Question**: What is the EBI Bone Healing System® Stimulator and how does it promote healing?
   Answer: The EBI Bone Healing System® Stimulator is an effective method for promoting the healing of fractures that have not mended spontaneously. The system consists of a treatment coil, which is incorporated into a cast, on top of a cast or brace, or placed directly on to the skin. The control unit delivers a therapeutic electric current to the treatment coil at the fracture site. Many events occur at the time of fracture to promote healing. Among them are your body's own natural electrical currents. However, if these natural electrical currents are interrupted, healing may become problematic. The therapeutic electrical current produced by the EBI Bone Healing System® Stimulator is very similar to the currents that the body produces naturally to signal the bone to begin healing in the first few weeks after your fracture. Just as you are unaware of the electrical currents produced by your own body, you may not be aware of the therapeutic electrical current produced by the EBI Bone Healing System® Stimulator.

2. **Question**: Is the system safe?
   Answer: The system has been widely used because of its proven success and absence of any known risks. It does not require surgery, has no known side effects, and is effective even in fractures where internal fixation devices such as rods or pins already exist.

3. **Question**: What is the usual healing time with this system?
   Answer: Since the EBI Bone Healing System® Stimulator triggers the bone healing process, the treatment period is similar to that expected following the surgical procedures for problem fractures. Your physician will determine the length of the treatment period based on the progress of your fracture. Your compliance with the recommended ten (10) hours per treatment is very important. A review of the clinical data demonstrates that less than the recommended use of the device possibly results in an increase in the time to heal your fracture. (P790002/S012)

4. **Question**: Is the treatment as effective as surgery?
   Answer: The success rate using the EBI Bone Healing System® Stimulator is comparable to surgical results without the risk associated with surgery.

5. **Question**: Is the cost of treatment covered by health insurance, Medicare or Medicaid?
   Answer: While the individual policies may differ in their coverage, most private insurance companies, health plans, or workers compensation plans have approved treatment with the EBI Bone Healing System® Stimulator. Coverage is also provided by Medicare and Medicaid.

6. **Question**: What will I feel during treatment?
   Answer: The EBI Bone Healing System® Stimulator should produce no sensations during its use. Should you have any questions, contact Biomet.

7. **Question**: How many hours per day will I have to apply the treatment coil?
   Answer: Follow the prescribed number of treatment hours instructed by your doctor (usually 3 to 10 hours per day).

8. **Question**: Can the EBI Bone Healing System® Stimulator be used if I become pregnant?
   Answer: Use of the Bone Healing System on pregnant patients has not been evaluated therefore, it is not recommended in these cases. If you become pregnant, notify your physician immediately.

9. **Question**: Is there any danger in wearing the treatment coil if I have a pacemaker or defibrillator?
   Answer: The unit is not recommended to be used with certain types of demand pacemakers or implantable defibrillators or in close proximity to a person with a pacemaker or defibrillator.

10. **Question**: If I extend the number of treatment hours per day, will it reduce the number of days required to heal my fracture?
    Answer: No, increasing the daily number of treatment hours beyond ten hours per day will not reduce the overall length of time to heal your fracture.

11. **Question**: Are there any side effects?
    Answer: None are known.

12. **Question**: Can I use an extension cord with the battery charger unit?
    Answer: Yes. (See GROUNDING PLUG - PAGE 4)

13. **Question**: What is the best way to store and transport the system? I travel a good deal and will be carrying the EBI Bone Healing System® Stimulator with me.
    Answer: It is recommended that you store and transport the control unit, battery charger, the link cable in the carrying bag for the best device protection.

14. **Question**: I turned the control unit on and the display reads, “RECHARGE BATTERY”. Do I have to wait, or can I use the system now?
    Answer: You may treat with the system while it is charging but before it is fully recharged. Leave the control unit connected to the battery charger. Make sure the control unit is on. This is called treating and recharging at the same time. The display will read “TREATING 00:00 AND CHARGING”.